

Progress report Updated November 2001

ACCELERATING ACCESS TO HIV/AIDS CARE, TREATMENT AND SUPPORT*

Background

Accelerating access emerged out of the partnership initiated in May 2000 between the UN (UNFPA, UNICEF, WHO, the World Bank and UNAIDS Secretariat,) and five pharmaceutical companies (Boehringer Ingelheim GmbH, Bristol-Myers Squibb, GlaxoSmithKline, Merck & Co., Inc., and F. Hoffmann-La Roche Ltd) to increase access to HIV/AIDS care, treatment and support.

As set out in the May 2000 Joint Statement of Intent, the UN/industry partnership was based on a set of broad principles, as follows:

- (i) unequivocal and ongoing political commitment by national governments
- (ii) strengthened national capacity
- (iii) engagement of all sectors of national society and the global community
- (iv) efficient, reliable and secure distribution systems
- (v) significant additional funding from new national and international sources
- (vi) continued investment in research and development by the pharmaceutical industry

Accelerating access has involved dialogue between the UN and the pharmaceutical industry to make quality drugs more affordable in developing countries, technical collaboration with countries in the development of national programme capacity to deliver care, treatment and support as well as consultation with governments and NGOs through a Contact Group.

While this is a collaborative process, legal obligations require the companies to continue to act individually and independently, particularly involving matters relating to the discovery, development and commercialization of products for the treatment or prevention of HIV/AIDS and related opportunistic infections.

Progress

UN/industry partnership

Abbott Laboratories and Pfizer Inc., together with four of the five companies signing the Joint Statement of Intent in May 2000 (Merck did not attend) participated in the meeting in Amsterdam in April 2001 with the Secretary-General, called to discuss options for intensifying the joint UN/industry contribution to increase access to HIV medicines and treatments (final statements from this meeting are attached). A subsequent meeting in Geneva in July 2001 between UNAIDS Cosponsors and Secretariat and industry to discuss progress and future steps in accelerating access involved representation from all seven companies.

Since the Amsterdam meeting, the companies, acting individually, have adopted a number of approaches to expand access to health care. These include: (a) continued and accelerated initiatives to make HIV/AIDS-related drugs more affordable to developing countries, particularly in sub-Saharan Africa; (b) enhanced partnerships with qualified non-governmental organizations and appropriate private companies offering health care to employees and local communities; and (c) concerted efforts to provide the necessary training to local health practitioners. Lower prices for groups of Least Developed Countries have

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been agreed with some companies individually and there have been a number of initiatives by individual industry partners to broaden access in the private sector and shipments have been made at the lowest prices to a number of eligible countries.

There have also been initiatives undertaken to expand donation programmes – with no cost or time limitations – to eligible countries and NGOs. With respect to affordability, companies, acting individually, have made specific public offers to supply some products at no profit, below cost, or free to qualifying countries.

In addition to renewed efforts to expand affordable access to antiretrovirals and other HIV-related medicines, each of the companies has built on existing initiatives and implemented broader partnerships, working with a wide range of countries, NGOs and health care organizations in developing countries to improve access to HIV care and treatment. These programs include efforts to train health care professionals, to build health infrastructure and capacity, to strengthen the role of NGOs in the continuum of care and to implement interventions designed to prevent mother-to-child transmission of HIV and to treat other targeted populations

The Geneva meeting reviewed progress towards achieving the commitments made in Amsterdam and highlighted several areas for further attention, including the need for expanded financing and health system development, regional collaboration, and increased affordability of drugs and diagnostics. Industry indicated it would welcome broadening the partnership to include companies that market generic drugs consistent with international agreements. It was agreed that intellectual property protection is key to bringing forward urgently needed new medicines, vaccines and diagnostics and the companies continue their efforts to discover and develop these new technologies. It was also agreed that a more positive view of the partnership and its achievements should be portrayed. This could highlight examples of effective cooperation at country and global level. The companies have indicated that they must operate within the provisions of anti-trust legislation.

Progress at country level

By mid-September 2001, 71 countries had indicated their interest in collaborating with UNAIDS on access to care and support, comprising 40 countries in Africa, 24 in Latin America and the Caribbean, 4 in Europe and 3 in Asia. A list of countries is attached.

Twenty six (26) of these countries have completed or are in the advanced stages of developing national care and treatment plans, most on the basis of some technical collaboration with the UN.

With involvement from UNAIDS, thirteen (13) of these countries – Burkina Faso, Burundi, Cameroon, Chile, Cote d'Ivoire, Gabon, Mali, Morocco, Romania, Rwanda, Senegal, Trinidad and Tobago and Uganda - have reached agreement with manufacturers on significantly reduced drug prices in the context of national plans. Individual companies have reported reaching agreement with four additional countries in the context of their accelerating access initiatives – Benin, Chad, Congo (Brazzaville) and Democratic Republic of Congo.

Significant price reductions have been achieved on an expanded range of HIV/AIDS medicines. Prices that have been publicly announced for Least Developed Countries in sub-Saharan Africa are set out in the Table attached. For some drugs, prices are higher outside sub-Saharan Africa (eg Morocco), albeit at price levels much lower than those in industrialised or high human development index (HDI) countries.

Regional collaboration

Because the country by country process of consultation on national AIDS plans and agreement on implementing antiretroviral therapy (including pricing discussions with individual companies) has been relatively slow and resource intensive, consideration has been given to developing a regional approach to expand the benefits more rapidly, for example through the possibility of bulk purchasing, shared technical assistance and joint resourcing. Regional

initiatives, involving the development of regional plans for care, treatment and support, are well under way in the Caribbean, Western and Southern Africa, and a first regional meeting on access is to be held this year in Southeast Asia. The UN is facilitating these efforts. Companies have indicated that they are comfortable with the concept of regional procurement, although principles and processes need to be explored further.

Recent UN actions

Assistance to countries

UNAIDS (Secretariat and Cosponsors) has been actively involved in facilitating greater access to care and treatment, assisting countries and governments identify options to increase care and support and supporting countries in the implementation of their chosen options. The number of countries seeking this support has doubled in a short period, from 35 in early May to over 70 now. Recent support for regional and sub-regional collaborations in part explains this rapid growth. A network of some 60 consultants from African and American countries, covering various disciplines, has been appointed and trained to speed up the process of country support. In providing assistance to countries, the UN continues to press its broad objective, to enhance progressively the capacity of countries to increase access to, and use of, sustainable, comprehensive and quality HIV/AIDS interventions across the entire spectrum of prevention, treatment, and patient care and support, including prevention of perinatal transmission.

Consistent with its mandate for advocacy and facilitation, UNAIDS has also been involved in mobilizing the vastly increased resources needed for care and treatment, in particular supporting consultations on the establishment of the Global AIDS and Health Fund and encouraging the flow of debt relief funds towards HIV/AIDS prevention and care programmes.

The World Bank's Multi Country HIV/AIDS Prevention and Control Programme (MAP) has recently approved a package of IBRD loans and IDA grants for several Caribbean countries and has agreed that, under certain conditions, parts of these loans may be assigned to the purchase of antiretroviral drugs. Barbados has been the first country fulfilling these conditions and therefore able to draw on World Bank loan funds to finance access to antiretrovirals. While MAP Phase I objectives in Africa cover capacity building for HIV/AIDS activities, including the infrastructure to facilitate access to treatment, MAP Phase II will more directly address access in selected countries.

Prevention of mother to child transmission

UNICEF is a key partner in UN efforts to implement programmes for the prevention of mother to child transmission of HIV/AIDS (PMCT). Such programmes are becoming more possible in resource poor settings with price reductions and donations of antiretroviral drugs. Programmes are now fully operational at 79 sites and in two national programmes in 16 countries, in Africa, Asia, Central and Eastern Europe and Latin America. Since the beginning of the pilot phase in Botswana and Rwanda in April 1999 up to July 2001, globally over 300,000 women have been reached, 220,000 have been counselled, 138,000 have been HIV tested and out of the 11,400 HIV positive mothers identified, over 4,500 have received antiretroviral therapy.

There is scope for improving provision of care and treatment so that more women with the potential to benefit have access to these interventions. There is also growing interest in offering "no test" Nevirapine to women whose HIV status is unknown at the time of delivery. HIV testing can be offered postpartum when it is particularly important to inform infant feeding choices. Recognising that women may be reluctant to be tested, PMCT Plus has emerged, proposing to provide women and mothers with ongoing care that may include antiretrovirals for the mother. One of the key issues in making such efforts feasible will be the training of health care workers in the care of HIV positive mothers, an effort where collaboration with the pharmaceutical industry may not only improve care delivery but assist in ensuring proper use of donated and price reduced antiretrovirals.

Tools and guidance

In May 2001, WHO convened a consultative meeting on the use of antiretroviral drugs in resource limited settings. Representatives from the pharmaceutical industry were not invited to participate in this discussion. Following this meeting, two technical working groups have been formed which are working on the development of simplified ARV treatment guidelines and the creation of a surveillance network for ARV drug resistance.

Current pricing information and data on suppliers is publicly available in "*Sources and prices of selected drugs and diagnostics for people living with HIV/AIDS*", a document produced by WHO, UNICEF, the UNAIDS Secretariat and MSF in June 2001. As the document points out, there are some limitations on the information provided in the report, which draws attention to the importance of quality assurance for pharmaceutical products.

In the context of dramatically increasing access to and affordability of HIV/AIDS related care and treatment, WHO, UNICEF, UNAIDS and UNFPA, supported by the World Bank, recently issued a second invitation to manufacturers of pharmaceutical products for the management of HIV-related diseases, to submit product dossiers for various dosages and strengths of the products in categories listed on the UNICEF Supply Division website.

Other WHO initiatives which serve to reinforce efforts to increase access to quality HIV/AIDS care, treatment and support include the production of a practical guide on the use of Nevirapine in the prevention of mother to child transmission and, in association with UNAIDS, UNFPA, UNICEF and the World Bank, a major project on pre-qualification, designed to ensure the pre-qualification of suppliers of HIV/AIDS related pharmaceutical products, to set up a model quality assurance system for procurement of pharmaceuticals, and to set out guidelines on the quality of pharmaceutical products related to HIV/AIDS. A joint WHO/WTO workshop on differential pricing in April 2001 explored the conditions required to bring into effect differential pricing for essential drugs. Further work on this is being pursued in collaboration with the TRIPS Council of the WTO.

Recent industry initiatives

Abbott Laboratories

Abbott Laboratories is committed to addressing the multi-faceted HIV/AIDS pandemic on multiple fronts. This commitment includes programmes that broaden access to therapy and assist those most directly affected by HIV/AIDS. Abbott research has led to the development of two widely prescribed protease inhibitors and numerous diagnostic products for HIV detection and therapy monitoring. While research remains a primary objective, Abbott Laboratories has also embarked on programs to broaden access to HIV care and testing and a major philanthropic endeavor related to HIV/AIDS.

? **Abbott Access:** Abbott Laboratories has strengthened its commitment to provide two therapeutic products (Norvir and Kaletra) and a diagnostic test (Determine HIV) at no profit. The initial offering for nations in Africa has been extended to include the 50 least developed countries, as defined by the UN. The application process to receive discounted product under this initiative is managed by Axios International, a consultancy specializing in health care in the developing world. Abbott Access is extended to entities that can utilize the products as part of sound and sustainable healthcare programmes, such as governments, NGOs, United Nations organizations, other national and international health institutions, private employers, hospitals, clinics, and other providers. Organizations that have successfully completed the application process are now receiving products at substantial discounts to support programmes that broaden access to HIV/AIDS care and treatment.

? **Tanzanian Drug Access Initiative.** Abbott has made a special commitment to the United Republic of Tanzania to strengthen its capabilities in dealing with the problems of HIV/AIDS. In June 2001, the Abbott Laboratories Fund sponsored a workshop to assist the

Ministry of Health in the development of its HIV/AIDS action plan. Abbott is committed to helping Tanzania develop a comprehensive programme for HIV diagnosis, care, treatment and support. Programme support will include technical assistance, certain product donations and the provision of products through the Abbott Access initiative.

? Step Forward[†]: In June 2000 Abbott initiated the Step Forward programme, a philanthropic initiative to assist AIDS orphans and vulnerable children in developing nations deeply affected by the pandemic. Step Forward programmes have broad flexibility to provide support in the areas of healthcare, voluntary counseling and testing, education and basic needs. Financial support, healthcare products and human resources are employed to construct or strengthen new or existing programmes. In Tanzania, among other activities, Step Forward has utilized employee-volunteers to strengthen laboratory infrastructure as it seeks to extend the reach of voluntary counseling and testing programmes in a remote region of the country. In Burkina Faso and India Step Forward assists the International HIV/AIDS Alliance in programmes related to health services at pre-schools, income generating activities and the linking of social service organizations with prevention and care programmes. In recent months, Step Forward has funded the renovation of a building that has become the Romanian-American Children's Center in Constanta through its partnership with Baylor University. As part of this programme Abbott is donating its antiretroviral therapies to as many as 500 children in that community. Renovation of the children's ward at Constanta Municipal Hospital and the purchase and renovation of a family home for abandoned children living with HIV/AIDS have also been completed.

Bristol-Myers Squibb

The mission of Bristol-Myers Squibb, a world leader in pharmaceutical development and infectious disease research, is to extend and enhance human life. The worldwide HIV/AIDS epidemic is a major area of focus for the Company. Besides the marketing of two anti-HIV therapies, VIDEX[®] (didanosine) and ZERIT[®] (stavudine), which are members of the class of antiretrovirals known as non-nucleoside reverse transcriptase inhibitors that form the backbone of Highly Active AntiRetroviral Therapy (HAART), Bristol-Myers Squibb is conducting an ambitious research programme identifying and developing new classes of anti-HIV drugs as well as investigating ways to make its current therapies simpler and more tolerable for people with HIV.

Drug discovery and development of medicines are only two parts of the company's commitment to solving the global HIV/AIDS crisis. Around the world, Bristol-Myers Squibb is supporting innovative programmes and outreach to those communities most devastated by the disease.

Secure the future

In 1999, Bristol-Myers Squibb pledged an unprecedented \$100 million over 5 years to address the HIV/AIDS epidemic in the countries of South Africa, Namibia, Lesotho, Swaziland and Botswana through a programme called Secure the Future: Care and Support for Women and Children with HIV/AIDS. In 2001, an additional \$15 million was pledged to the West African nations of Senegal, Cote d'Ivoire, Mali and Burkina Faso. The largest corporate commitment to date, Secure The Future has two components: one involving Medical Research grants provided through the Bristol-Myers Squibb Pharmaceutical Research Institute which seek to support innovative, therapeutic research by local scientists and doctors to increase the capacity of the countries to manage the epidemic, and the other focusing on Community Outreach and Education grants provided by the Bristol-Myers Squibb Foundation, which help communities more effectively assist people living with HIV/AIDS by building on

[†] The Step Forward program is an initiative of Abbott Laboratories and a philanthropic arm of the company known as the Abbott Laboratories Fund.

existing resources or expand or improve upon existing efforts to work against HIV/AIDS and its social consequences.

The Secure the Future initiative seeks to develop local capacity that will allow local organizations and individuals to address the HIV/AIDS epidemic in a sustainable way. To date, Secure the Future has approved 68 grants totaling over \$50 million in committed funds. A few examples of Secure the Future projects are:

Medical research grants

- In Botswana, Secure the Future partnered with the national government and the Harvard AIDS Institute to create a technologically advanced laboratory on the grounds of the country's biggest hospital, the Princess Marina Hospital. The laboratory's projects include: skills transfer and capacity development, the improvement of tools for monitoring HIV/AIDS, the first large-scale research study of antiretroviral therapy to treat AIDS and HIV infection in Botswana, assessment of resistance depending on regimen and adherence strategy and research on a possible vaccine.
- Investigating an improved and cost-effective alternative approach for the generation of CD4 cell counts to monitor response to HIV/AIDS therapy, Secure the Future provided a grant to the South African Institute for Medical Research at the University of Witwatersrand in South Africa. Results from this project have identified a more cost effective and accurate method to enumerate CD4 cells, with less technological expertise needed, which may prove highly valuable in resource-limited settings.
- At the Chris Hani Baragwanath Hospital in Soweto, South Africa, reportedly the largest in the world, a grant from Secure the Future to the hospital's Perinatal HIV Research Unit is enrolling willing women who did not receive antiretroviral treatment during pregnancy or delivery and women who were diagnosed as being HIV infected post-delivery in a study to see whether a postpartum treatment regimen for the babies can be effective in preventing their infection by the HIV/AIDS virus.
- Students at nursing colleges across the sub-Saharan region will be studying the management of HIV/AIDS by way of a new curriculum developed with the support of a Secure the Future grant and Baylor College of Medicine. The curriculum, which is being translated into French, covers a broad spectrum of areas needed to understand the complexities of HIV/AIDS management, such as epidemiology, pathophysiology, testing and counseling, antiretroviral treatment and psychosocial, legal and ethical issues. Nursing associations from across Africa have expressed interest in using the curriculum for the training of nurses in their countries.

Community outreach and education

- Secure the Future has supported a two-year master's programme in HIV/AIDS policy at the School of Public Health at the Medical University of Southern Africa (MEDUNSA). To date, more than 100 people are enrolled in the programme, many of whom are already playing key roles in formulating their countries' and their communities' policies on dealing with the epidemic.
- In Swaziland, the fund is helping to mobilize local non-governmental organizations by supporting an eight-module training programme to build the organizations' capacity to deal with HIV/AIDS-related projects. In May 2001, 80 organization members, including pastors in church-based efforts and youth activists, received certificates from the Institute.
- Also in Swaziland, the fund, in partnership with Cabrini Mission Foundation, has helped support training in home-based care dealing with HIV/AIDS for a cadre of 2,500 community health workers known as Rural Health Motivators who represent the backbone of that country's health care system. This group works against the stigma associated with HIV/AIDS that has prevented many community residents from seeking treatment.
- Secure the Future has also helped support the Reetsanang Association of Community Drama Groups, a Botswanan organization that travels across the country especially to marginalized and remote rural areas, conducting participatory HIV/AIDS education workshops and interactive theater performances that air community issues. The goal of the programme is to destigmatize and mobilize through key HIV/AIDS intervention messages.

- In South Africa, Secure the Future is supporting the Bambisanani Project, an effort in three poverty-stricken rural areas in the Eastern Cape Province to provide an integrated approach to support people living with HIV/AIDS and their families. The efforts include identifying and training community care supporters and primary caregivers at home, building drop-in centers to house support groups and income-generating activities and conducting a study of children in distress as a result of the disease.
- In Lesotho, a Secure the Future-funded grant supports a project in partnership with the Cooperative for Assistance and Relief Everywhere (CARE) addressing HIV/AIDS destigmatization through peer education and prevention tactics among women and children in the border towns of Lesotho and South Africa.
- Building a national lay counseling capacity in Northwest Namibia is the focus of another grant from Secure the Future. The project plan covers community consultations with key opinion leaders, traditional leaders, community-based organizations, women's organizations and government, as well as the training of community-based lay counselors and volunteers.

Thailand

The Thai Red Cross, with the support of the Bristol-Myers Squibb Foundation, is preparing a multiyear effort to help children living in slum communities acquire skills they can use to protect themselves against HIV/AIDS. In Bangkok, there are roughly 300,000 children living in such communities, where the children are highly exposed to the AIDS virus through unprotected sex and sex with commercial sex workers. The AIDS Research Centre will train 500 children using a novel approach to behavior modification called life skills training. Life skills training involves the use of games, role playing and community theater to help participants gain skills in decision making, problem solving, critical thinking and communication. If the training programme proves successful, the Thai Red Cross hopes to extend it to other communities and to present it to the Thai Ministry of Health for possible use in national youth training.

Mexico

HIV/AIDS has created an urgent health crisis in Mexico, especially for the most vulnerable victims of the disease – children. Without access to lifesaving drugs or a comprehensive system for managing the disease, Mexican children with HIV/AIDS have faced a future of degradation, despair and early death. The Bristol-Myers Squibb Foundation has responded to this crisis by joining hands with the Hospital Infantil and other partners in Mexico to develop innovative programmes to treat children with AIDS as well as to help prevent the further spread of the disease. With training assistance from Baylor College of Medicine in Houston, TX, local medical facilities are being established or improved to better diagnose and treat the disease. Additionally, the Foundation-sponsored programme is educating women – particularly pregnant women and women of childbearing age – on prevention of HIV/AIDS, including the importance of screening. The aim is to break the cycle of infection that is threatening to make HIV/AIDS an even greater public health menace in Mexico. Finally, the programme helps bring lifesaving medicines to the children who need them so desperately.

UN/Industry Accelerating Access Initiative (AAI)

Bristol-Myers Squibb has been a strong participant in the AAI since its inception more than 18 months ago. The Company has worked closely with UNAIDS and the other public sector agencies involved in the AAI (UNICEF, the World Bank, the WHO and UNFPA) as well as with the governments in developing countries who have indicated a willingness and desire to work with the AAI in developing and implementing national plans to expand access to sustainable prevention, care and treatment of HIV/AIDS. As part of its commitment, Bristol-Myers Squibb has offered its two antiretroviral medications, *Videx* and *Zerit* at discounts of up to 93% from the prices offered in the USA and Europe to developing countries that have reached agreement with UNAIDS on ways to expand access to ARV's for their citizens.

- On March 14, 2001, Bristol-Myers Squibb announced that it would make *Videx* (didanosine) and *Zerit* (stavudine) available to countries in sub-Saharan Africa who were

interested in implementing an expanded access to ARV programme in their country at a price that was below its costs. The combined price of *Videx* and *Zerit* would be \$1.00/day (\$0.85 / day for 400mg of *Videx*; \$0.15 / day for 80mg of *Zerit*). To date, the following 12 sub-Saharan African country governments have availed themselves of BMS' offer:

- Benin, Burkina Faso, Burundi, Cameroon, Chad, Congo (Brazzaville), Côte d'Ivoire, Gabon, Mali, Rwanda, Senegal, Uganda
- In addition, this offer has been made available to any non-government organization, any charitable organization, any private-sector caregiver or to any private sector employer in sub-Saharan Africa able to deliver medically sound care and treatment all the while keeping the costs of this delivery as low as possible. *Videx* and *Zerit* are available in this way at \$1.00 / day in these additional 11 sub-Saharan African countries:
- Botswana, Kenya, Lesotho, Malawi, Mozambique, Namibia, South Africa, Swaziland, Tanzania, Zambia, Zimbabwe
- Vastly reduced prices on *Videx* and *Zerit* are now available in these 3 non-sub-Saharan African countries:
- Romania, Chile, Trinidad & Tobago
- Finally, on March 14, 2001, Bristol-Myers Squibb announced that it would ensure that its patents do not prevent inexpensive HIV/AIDS therapy in Africa.

Boehringer Ingelheim

Boehringer Ingelheim is committed to offering meaningful solutions in the worldwide fight against HIV/AIDS. The successful solutions offered to-date have included the discovery and development of new and innovative treatments for HIV infection, support of international efforts to expand access to appropriate therapies for the prevention and treatment of HIV infection in the developing world, and the improvement of health care capacity. Through these initiatives, Boehringer Ingelheim has established itself as a leader in the therapeutic arena of HIV infection.

Commitment to research

In the late 1980s, Boehringer Ingelheim invested in a large-scale discovery programme for therapeutic agents for the treatment of HIV infection. The first positive result from this programme was the discovery of VIRAMUNE (nevirapine). VIRAMUNE, approved for use for the chronic treatment of HIV infection in combination with two or more antiretrovirals in the USA in 1996, was the first agent in a new therapeutic class known as non-nucleoside reverse transcriptase inhibitors. In addition to its novel mechanism of action, it was the first approved antiretroviral without the nucleoside structure of AZT. The availability of VIRAMUNE represented a breakthrough in the treatment of HIV, as it represented the first opportunity to combine drugs with different mechanisms of action and non-overlapping toxicities, thus paving the way for true combination therapy.

In January 2000, Boehringer Ingelheim announced that the company had in-licensed tipranavir from the Pharmacia Corporation. Tipranavir is the first agent in a new class of therapeutic drugs called non-peptidic protease inhibitors. The unique and important feature of tipranavir is that it retains potent antiviral activity against strains of HIV that have demonstrated resistance to all of the currently marketed protease inhibitors. This drug represents a potential breakthrough therapy, in that it offers the possibility of potent antiretroviral efficacy for patients that are refractory to available therapies due to multi-drug viral resistance.

Boehringer Ingelheim continues to invest heavily into the discovery of new therapeutic agents for the treatment of HIV infection and other virologic infections. Discovery of new drugs has

been focused in Boehringer Ingelheim's research facilities located in Canada, which specializes in the areas of HIV and virology research.

Expansion of access to treatment in the developing world

Boehringer Ingelheim was one of the founding pharmaceutical company partners in the Accelerating Access to HIV Care, Treatment and Support programme. Since the time that Senegal announced its participation as the first country in the Accelerating Access initiative, Boehringer Ingelheim has offered VIRAMUNE at a wholesale price of US\$ 0.60 per tablet. This offer is available to 77 developing countries, including countries in sub-Saharan Africa, countries included in the low-income economy classification by the World Bank Classification of Economies, and countries on the list of Least Developed Countries (UNCTAD). This offer has been made to governments, non-governmental organizations, and other health care providers in these countries with the means to use the drug in a safe and effective manner consistent with its prescribing information. The price offered to these countries represents a reduction of approximately 90% relative to the price of VIRAMUNE in the developed countries.

In addition, Boehringer Ingelheim is committed to offering preferential pricing to countries included in the lower middle-income and upper-middle income economies according to the World Bank Classification of Economies. The price of VIRAMUNE in these countries will be determined on a country-by-country basis taking into account the economic situation of the country, as well as the extent of the HIV epidemic.

Expansion of access to prevention in the developing world

The safety and efficacy of VIRAMUNE for the prevention of mother-to-child transmission of HIV (MTCT) was demonstrated in a series of clinical trials conducted in the developed and developing world. The trials were organized and sponsored by the ACTG and HIVNET organizations together in cooperation with Boehringer Ingelheim. Subsequent to the availability of the results of these trials, Boehringer Ingelheim sponsored and performed a landmark clinical trial investigating the use of VIRAMUNE for the prevention of MTCT that was conducted in South Africa. This trial, known as the SAINT study, is today still collecting important information about the use of VIRAMUNE for this purpose.

Following the availability of the results from a clinical trial conducted in Uganda called HIVNET 012, Boehringer Ingelheim recognized the potentially dramatic public health consequences associated with the use of VIRAMUNE for the prevention of MTCT in the developing world. As a consequence, in July 2000, Boehringer Ingelheim announced the VIRAMUNE® Donation Programme for the Prevention of Mother-to-Child Transmission of HIV-1. This programme represents the company's commitment to provide VIRAMUNE (nevirapine) free-of-charge for a period of five years to developing countries. The objective of this programme is to remove the barrier of cost as an obstacle for the use of VIRAMUNE for this purpose.

Boehringer Ingelheim, together with a third-party consultant, Axios International, has developed an application process that is designed to provide the confidence that the donated drug will reach the patients that it is intended to help. Applicants are strongly encouraged to use the donated drug in the context of a comprehensive mother-to-child transmission prevention programme, as is consistent with the recommendations of the UN family of agencies. The company shares the vision of the UN that comprehensive MTCT prevention programmes, including the prophylactic use of antiretrovirals, will provide a sustained benefit for the affected community.

Following the initial announcement of Boehringer Ingelheim's commitment to donate VIRAMUNE, there was not an overwhelming number of requests from interested governments, NGOs and other health care providers to participate in the programme. The number of applicants has, however, increased dramatically in the past several months. Boehringer Ingelheim has now approved 29 applications from 18 countries in Africa, Eastern

Europe, and the Caribbean, for which the company has committed to deliver approximately 62,700 treatments.

Based upon the experiences to-date, the lag time in receiving applications appears to have been related to the difficulties in many of these countries to provide access to the health care capacity necessary to use even this simple therapy in the context of a comprehensive MTCT prevention programme. As awareness and interest concerning the establishment of comprehensive programs increased, so did the interest in the VIRAMUNE Donation Programme. The experience in the VIRAMUNE Donation Programme is likely to be analogous to that which will be seen in the broader area of access to antiretrovirals for chronic treatment; namely, significant expansion of access to these medicines will be preceded by interest and investment into the development of infrastructure and services that generally increase access to health care. In short, expanding access to health care is a prerequisite to expanding access to medicines.

Capacity building

Boehringer Ingelheim and its affiliate companies around the world are contributing to the overall goal of expanding and improving health care capacity in developing countries. Some selected examples include:

- Sponsorship of HIV information and prevention programmes in Papua New Guinea
- Sponsorship of an innovative information campaign for HIV patients in Eastern Europe called "Breaking the Silence"
- Financial sponsorship of programmes aimed at defending basic rights of children, including access to quality health care in Brazil
- Donation of free drugs to a variety of charitable organizations involved in the fight against HIV/AIDS in France
- Financial support of various projects in the developing world through the auspices of the German Pharma Health Fund
- Financial support of underprivileged students at the University of Cape Town, South Africa
- Sponsoring educational programmes for GPs throughout South Africa on HIV/AIDS treatment regimes
- Sponsorship of an HIV/AIDS clinic in the Northern Province of South Africa in conjunction with Nelson Mandela and the Catholic Church
- Continued investment in South Africa into studies of the efficacy and safety of VIRAMUNE for the prevention of MTCT
- Financial support of the Elizabeth Glaser Pediatric AIDS Foundation in the USA
- Donation of VIRAMUNE in the USA through relief organizations, including Americares, Catholic Medical Mission Board, and MAP International

The meaningful solutions in the fight against HIV/AIDS offered by Boehringer Ingelheim are a direct reflection of the company's recognition of its social responsibility as a leader in the area of HIV therapy. At the same time, Boehringer Ingelheim recognizes that, as a company whose primary mandate is the discovery and development of new and innovative therapies for HIV infection, it cannot win the fight alone. The company has stepped forward to offer what it can and hopes that, by its example, other key stakeholders will join in partnership in order to address the pandemic of HIV infection.

GlaxoSmithKline

GlaxoSmithKline (GSK) was formed by the merger of GlaxoWellcome and SmithKline Beecham in December 2000. GSK's commitment to improving healthcare in the developing world incorporates three essential elements: investment in the research and development of new medicines and vaccines for diseases that affect the developing world; sustainable preferential pricing arrangements in Least Developed Countries and sub-Saharan Africa for currently available medicines needed most; and a leading role in community activities that

promote effective healthcare. GSK's approach is underpinned by a series of key principles - sustainability, appropriate use, support for innovation, partnership, and shared responsibilities.

GSK's commitments are fully manifested in our activities on HIV/AIDS.

Commitment to research and development

GlaxoSmithKline has a long-standing commitment to R&D for medicines to treat diseases prevalent in the developing world, with more than 20 active projects ongoing. GSK is the only company currently involved in research and development for both prevention and treatment of all three top priority diseases of the World Health Organization: malaria, tuberculosis and HIV/AIDS.

GlaxoSmithKline's has had a pioneering role in HIV medicines and vaccines. Glaxo Wellcome (GW) introduced Retrovir (AZT), the first anti-retroviral therapy, in 1986. Retrovir was the only medication available to treat HIV infection until 1991. In 1995 we introduced Epivir (3TC) and, in order to help patients to adhere to complex regimens, Combivir (AZT/3TC) was introduced in 1997. Combination therapy for HIV has resulted in significant improvements in the treatment of the disease.

The company's growing expertise in HIV/AIDS drug discovery and development resulted in the introduction in 1998 of two new treatments for HIV infection, Ziagen (abacavir) a nucleoside analogue and Agenerase (amprenavir), a protease inhibitor. This was followed in 1999 by Trizivir, which combines the active ingredients of Retrovir, Epivir and Ziagen in only one tablet taken twice daily. This is a significant improvement over current therapies which can mean taking up to 20 tablets a day.

GSK has clinical projects under way with a new combination medicine and a novel protease inhibitor, an integrase inhibitor, through a Joint-Venture with Shionogi, as well as basic research efforts to discover additional medicines with novel mechanisms.

GSK's HIV candidate vaccine has moved into clinical trials in the US Government's National Institutes of Health HIV Vaccine Trials Network. It is hoped this vaccine will be effective against clade B. GSK will also be developing an HIV vaccine for use internationally, targeting at least one other strain circulating in Africa and Asia.

GSK has been involved in 33 clinical trials conducted to reduce the risk of mother to child transmission (MTCT) of HIV and is committed to facilitate further research to progress and improve the efficacy of interventions. Results from these are now being implemented via UNICEF-initiated MTCT drug access programmes.

Currently, GSK supports 29 HIV clinical trials in developing countries. These are conducted in collaboration with other pharmaceutical companies, local governments or organisations and academics and each study undergoes local ethical committee review and approval. Within this framework, new clinical centres of excellence are being developed and research studies are being supported to assess the most appropriate way to use anti-retroviral therapy in resource poor settings.

Sustainable preferential pricing

GW offered significantly discounted prices for Retrovir, Epivir, and Combivir since 1997 for MTCT programmes in sub-Saharan Africa.

In May 2000, GW expanded preferential pricing for those medicines in developing countries through the Accelerating Access Initiative (AAI). The AAI has involved close partnership with our UN partners, especially UNAIDS, developing countries, and our other pharmaceutical companies. Seventy-one countries have registered their interest in the programme to UNAIDS, 18 countries have produced national HIV/AIDS care and treatment plans and have

concluded preferential pricing arrangements with partner companies. Treatment numbers are expected to increase by three to four fold in each of these countries.

On 11 June 2001 GlaxoSmithKline announced a number of new commitments to address the challenge of HIV/AIDS and other diseases of the developing world. Many of these commitments were directly in line with the objectives set out in an industry meeting with UN Secretary General Kofi Annan in Amsterdam in April 2001. The new commitments were:

1. Expanded Range of HIV/AIDS Products for Preferential Pricing

The company already made three established HIV/AIDS medicines - Retrovir, Epivir and Combivir - available at up to a 90% discount from the world average price. GSK is now also offering Ziagen, Trizivir, and Agenerase at preferential prices. In all markets where GSK products are available, the company is working with governments and other partners to ensure its products are used appropriately and effectively by the patients for whom they are intended.

2. Expansion of Countries Eligible for Preferential Pricing Offers

GSK is offering all of its HIV/AIDS medicines at preferential prices to all countries in Sub-Saharan Africa and all Least Developed Countries (LDC) as identified by the United Nations - a combined total of 63 countries. The prices available to these countries are fixed single prices and are not for profit.

The company's HIV/AIDS medicines will also be available at discounted prices to other countries that join the Accelerating Access Initiative. GSK will also continue to work on a case-by-case basis with middle income developing countries to negotiate public sector prices that maximise affordability for governments in their treatment programmes.

3. Expansion of Customer Groups Eligible for Preferential Pricing Offers

GSK has extended its preferential pricing offer for HIV/AIDS medicines beyond Governments to include not-for-profit non-governmental organisations (NGOs), such as international agencies, aid groups, churches and charities that have the facilities in place to appropriately monitor and treat patients. In recognition of the gravity of the HIV/AIDS situation in Sub-Saharan Africa, GSK is also offering preferential prices on anti-retroviral therapy to employers in Africa which offer HIV/AIDS care and treatment directly to their staff through their own workplace clinics. GSK has also extended its preferential pricing offer for HIV/AIDS medicines to include any international health funds, such as the Global Fund for AIDS, Tuberculosis, and Malaria, that may be set up.

Community activities to combat HIV/AIDS

Positive Action

Positive Action is GSK's international programme of HIV education, care, and community support. Through the programme, GSK works in partnership with individuals, community groups, healthcare providers, governments, international agencies, and others in order to build on the success of community initiatives and pursue the common goals. Since its inception in 1992, Positive Action has supported and implemented a wide variety of projects at both a national and international level, throughout 49 countries in the developing and developed world. These include:

Community involvement in initiatives to prevent MTCT of HIV

Since 1998, the company has been collaborating with UNICEF and UNAIDS on a UN-led international programme to provide MTCT in developing countries by providing the initial free start up supply of *Retrovir* (30,000 treatments or 2.5 million tablets). The programme has been extended from the original 11 countries to 25. The country programmes will then progress to access based on preferentially priced medicines. In 1999, Positive Action established a programme with the Population Council and the International Center for Research on Women to identify information and social needs required to support MTCT pilot

programmes. The programme describes the barriers to voluntary counselling and testing, stigma and fear of HIV disclosure, community/cultural reluctance to embracing breast milk substitutes, and role of mothers in a patriarchal society.

Community Lessons Global Learning

From 1997 to 2000 GSK supported a three-year International HIV/AIDS Alliance programme to encourage sharing of best practise amongst community groups from Asia, Latin America and Africa. The programme centred on a series of direct, intensive country and regional training seminars, bringing together local groups and experts. The materials resulting from the programme are acknowledged as the gold standard of community responses to AIDS.

Centre for African Family Studies (CAFS)

In September 2000, (CAFS) in partnership with Positive Action launched an initiative for the organisational development of community-based groups and networks of people living with HIV/AIDS (PLWHAs). The aim was to increase the participation of PLWHAs in national and international HIV/AIDS policy discussions by strengthening their capacity in Africa. The project was initiated in three countries, Kenya, Ethiopia and Togo. During the first year, multiple level partnerships were established through the formation of Regional Advisory Groups, National Consultative Groups and Local Focal persons. By August 2001, six training modules (English and French) for chief executives, staff and volunteers of PLWHA community based groups have been developed to cover: Advocacy and Fundraising, Networking and Communication and Management and Leadership.

International Community of Women Living with HIV/AIDS (ICW): A Positive Woman's Survival Kit

A Positive Woman's Survival Kit is a Positive Action project developed over 1998/1999 in partnership with ICW. The programme aims to provide information to women globally who are living with HIV/AIDS, with a particular focus on marginalised women who have little access to information and support locally. The Survival Kit aims to provide HIV-positive women with information, support and resources on planning for the future, nutrition, healthcare and other issues related to HIV positive women. The Survival Kit was launched in English and has subsequently been translated into French, Spanish and Russian with versions planned for Polish, Portuguese, Greek, Thai, Tamil, Hindi and Swahili.

GSK France Foundation

GSK France Foundation was started in August 1998 to improve prevention, education, training, and care in the area of infectious diseases. Current programmes aim to provide support in facilitating better access to care and treatment for people living with HIV in developing countries. Seventeen programmes are under way in 7 countries: Ivory Coast, Senegal, South Africa, Morocco, Cameroon, Mali, and Burkina Faso. The total number of people that will be affected by these programmes are 150,000 people (mainly women) via access to voluntary testing (VCT) and adequate antenatal care and 7,500 people (women, children, and men) via access to follow-up care.

South Africa: Helping communities to help themselves

GSK's South African Corporate Social Investment (CSI) programme is geared towards the improvement of the health and well being of all South Africans, children in particular. In all programmes, the department of health, NGO's and black empowerment groups are key partners. In addition to funding, GSK key employees play an active role in programme initiatives.

HIV infant Care Programme

Since 1999, GSK South Africa has supported the HIV Infant Care Programme (HIC) which was established to effectively mobilise, capacitate, and train communities to care for their babies and children who are living with HIV/AIDS – nearly 2 million South Africans under the age of 25 are HIV-positive.

AIDS Care, Training and Support Clinic (ACTS)

A new HIV/AIDS clinic opened in 2001 in the Masoyi tribal area of Mpumalanga, South Africa, with funding and support from GSK South Africa. This project is committed to the care and

support of those infected with HIV/AIDS as well as other diseases, and to the training of both professionals and volunteers. The clinic, which features two consulting rooms, a physiotherapy room, kitchen, dispensary and waiting area, will provide a place where the community can go for testing and receive counselling, support and treatment, and is part of a three-year, £300,000 GSK programme designed to provide a quality continuum of care to all those in the region who are infected and affected by HIV/AIDS. The goal is to establish a cost-effective model of care that could potentially be replicated elsewhere in Africa.

Innovative partnerships

Voluntary licensing

Recognizing that innovative approaches to the HIV/AIDS pandemic can lead to enhanced treatment opportunities, GSK granted a voluntary license for the manufacture and sale within South Africa to Aspen Pharmacare for three of GSK's most extensively used antiretrovirals, zidovudine, lamivudine, and combinations containing those products. Shire Pharmaceuticals Group, the holders of patents relating to lamivudine, and GSK, the holder of patents relating to zidovudine have agreed to waive their rights to royalty payments on these products. Aspen will sell these discounted anti-retrovirals to the South African public sector, NGOs and other charitable organisations. In addition, a 30% fee on net sales will be donated to NGOs that manage programmes related to HIV/AIDS in South Africa. It is hoped that this partnership will contribute to a total healthcare solution for HIV/AIDS within South Africa. GSK will continue to work with key stakeholders on innovative partnerships to address the HIV/AIDS pandemic and look forward to assessing the potential success of this voluntary licensing arrangement.

Alpha Roundtable

GSK facilitated the "Africa's Leading Priorities in HIV/AIDS" (ALPHA) Roundtable which brought together a group of experts who are all practising physicians in Africa with first-hand experience of the management of HIV/AIDS. The purpose of the meeting was to develop a consensus on the priority actions relating to healthcare delivery that are needed to address most effectively the HIV/AIDS pandemic in Africa and to apportion funding accordingly. Output of the roundtable will be communicated to all interested stakeholders in December 2001.

F. Hoffmann La-Roche Ltd

Roche is a company with a strong dedication to healthcare, our core being the discovery, development and provision of life-saving therapies and diagnostic tests to address the HIV epidemic. Roche believes that drug price is only one of the many barriers to care and that the building and sharing of knowledge at all levels is crucial to the prevention and management of HIV/AIDS. There is no simple or single solution that works for everyone and it is clear that no person, country, organization or company can hope to defeat HIV and AIDS alone. Instead, we all need to work together in a holistic way that addresses local community needs, to find the solutions that will make a difference to the lives of people living with HIV.

- **Research commitment**

In addition to the provision of a broad range of HIV treatments currently used in HIV and AIDS therapy, Roche invests significantly in HIV research and development.

- Roche's research effort is ongoing globally to **find better drugs, optimal regimens** to prolong the use of existing treatments, **improved formulations** and more **sensitive diagnostic tools (used to diagnose different strains and subtypes common in sub-Saharan Africa but rare in the developed world)**, to tackle the problem of rapid detection, early treatment, increased drug resistance and the challenges of adherence.
- Many people living with HIV are also infected with **hepatitis C** and Roche is currently developing a once-weekly, pegylated form of interferon, PEGASYS® (peginterferon alfa-2a) for the treatment of this condition. Similarly, coinfection with cytomegalovirus (CMV) can give rise to a severe eye disorder called CMV-retinitis. Roche provides

Cymevene for the treatment of CMV-retinitis and is currently launching Valcyte, a pro-drug of oral ganciclovir that has significantly greater convenience than Cymevene and can be used in place of the i.v.- ganciclovir induction phase of treatment.

- HIV is an unforgiving virus and there is an urgent need to find new treatment options with a different mechanism of action and which are effective against **multi-drug resistant HIV virus**. In collaboration with Progenics Pharmaceuticals Inc., USA and Trimeris Inc., USA, Roche aims to discover and develop new generations of anti-HIV drugs. Together, Roche and Trimeris are investing approximately half a billion US dollars to bring the most clinically advanced of these, the **fusion inhibitors**, to those people with HIV who most need them. Unlike traditional HIV/AIDS drugs, all of which work inside the already infected cell, fusion inhibitors attack HIV outside the cell thereby preventing fusion between the virus and the cell, the process that normally results in viral replication.

By combining its existing anti-HIV treatments and cutting-edge diagnostic technology with the potential of new research compounds, Roche is adopting an integrated approach to addressing the challenges of HIV and AIDS. In this way, Roche is committed to finding and delivering more effective long-term healthcare solutions to people living with HIV.

- **Partnership**

Collaboration is essential to the success of access programmes and Roche supports a variety of initiatives around the world designed to help build local capacity and resources to ensure long-term sustainable healthcare. Specific examples include:

1. In partnership with **PharmAccess International (PAI)[‡]**, Roche is already taking the first step to widening access to HIV therapy in Africa, in a controlled, clinically sound and sustainable way by focussing on the improvement and build-up of the local medical infrastructure. The goal is to **expand access to HIV therapy** for HIV-1 infected patients in Côte d'Ivoire, Kenya, Senegal and Uganda. The provision of the latest treatments for HIV and opportunistic infections (that are common in Africa but rare in developed world countries), training of healthcare professionals and patient education are key elements of this partnership initiative.
PAI is providing its medical and logistical expertise implementing clinical programmes in developing countries and Roche is providing full financial support for the programme to cover the costs of antiretroviral drugs, diagnostic and monitoring testing, training of healthcare professionals and patient education. The PAI access programme will also benefit from Roche's support and technical expertise in the areas of patient education, HIV prevention and counselling programmes, and training of local healthcare professionals to ensure that they are equipped to deliver the highest standards of HIV-related care. Supported by a series of workshops involving counsellors, lab technicians, pharmacists and African physicians partnered with European Physicians, newly acquired skills and knowledge will be shared and the programme cascaded through additional centres and beyond.

The programme also aims to establish the use of a potent, once-daily and cost-effective protease inhibition treatment strategy under local conditions. The treatment regimen to be studied includes the use of Roche's protease inhibitor, FORTOVASE® (saquinavir) on a once-daily basis, combined with a 'boosting' dose of ritonavir and the nucleoside analogues AZT and 3TC. The aim of this therapeutic approach is to enhance the convenience of HAART regimens and to further reduce the cost of therapy.

The pilot programme with 100 physicians/ healthcare professionals trained is just a beginning and provides a framework for the future addition of more patients. It is truly a cross-cultural endeavour – the draft protocol has been reviewed by African, European and North American physicians and has been submitted for approval to STEG (the Dutch national ethics committee) in the Netherlands and also to the African countries. The

[‡] PAI is a not-for-profit Dutch-American organization of independent healthcare professionals and is closely linked to the International Antiviral Therapy Evaluation centre (AMC-IATEC) at the Academic Medical Center in Amsterdam, The Netherlands

programme will be rolled out in the next 6 months and Roche will send auditors to visit clinical centres to support and troubleshoot to ensure a successful implementation of the programme. **It is anticipated that the first of the 200 patients in the initial phase will be enrolled in the next 2 months.** The initial phase of the programme will run for two years, following which the participating patients will continue to receive the medication under the same conditions while the scope of the programme is expected to be expanded into other centres and countries with funding from other international donors. The PAI's pilot cohort programme, CARE (Cohort programme to evaluate Access to anti-Retroviral therapy and Education), is designed to evaluate the effectiveness, safety and tolerability of a standard HAART regimen provided in 4 low-income settings to patients who would otherwise have no access to highly active antiretroviral therapy (HAART). In addition the cost-effectiveness of the therapy and the influence of patient disease education on compliance will be studied. An attempt will be made to evaluate the benefits of providing access to care on the quality-of-life of the patients, and on their ability to work. Health care personnel will be trained in order to give them an update of current international knowledge about HIV-management and to ensure that patients receive adequate medical care. The results of the pilot programme will be used to determine the feasibility of increasing access to antiretroviral therapy in developing countries. **The pilot has been designed so that every element can be amplified with the commitment and funding of other donors from the international community.**

2. Through its collaboration with **HIV-NAT**[§] in Thailand, Roche is focused on finding locally sustainable solutions that make a difference to the lives of people with HIV. The HIV-NAT clinical programme studies the efficacy and safety of different HIV treatment regimens under local conditions in Thai patients. The first study was completed in September 1996. The successful completion of the second study in 1997 attracted further interest and investment in the Centre and another nine trials are ongoing in Bangkok/Thailand sites with about 1,200 people with HIV now benefiting from effective treatment.

Through the help of supporters like Roche, the HIV-NAT programme is able to make drugs available to study participants and, through various schemes, continues to provide access to therapy beyond each study's completion. This commitment has ensured that all those involved with HIV-NAT trials are still benefiting from the most effective anti-HIV therapy.

Results from HIV-NAT research have recently been presented at an international HIV therapy workshop in the Netherlands in April 2001. The data provides further support for the investigational use of the soft gel capsule formulation of the protease inhibitor, FORTOVASE® (saquinavi), combined with a low booster dose of zidovudine to provide a potentially simplified and cost effective HIV treatment strategy.

Furthermore, Roche is donating saquinavir for 400 Thai patients in a structured therapy interruption (STI) study. The STACCATO study, to be conducted in Thailand, Australia, and Europe will look at the use of intermittent antiretroviral therapy to reduce costs of treatment as well as side effects.

HIV-NAT study results are shared with local HIV-treating physicians and Thai policy-makers and are also presented at international meetings. Results from HIV-NAT studies and those of international researchers were influential in the recent decision of the Ministry of Public Health (MOPH) to recommend triple antiretroviral therapy as standard of care in Thailand. This sharing of knowledge, combined with the increase in study-related income for those laboratories involved, is challenging and changing perceptions in Thailand about the treatment of HIV/AIDS and is further strengthening the country's HIV research and care infrastructure.

3. Roche has a long-standing involvement in the treatment of other sexually transmitted diseases (STDs). STDs are believed to constitute a confounding factor in the

[§] HIV-NAT is an international collaboration between the International Antiviral Therapy Evaluation Centre (IATEC) in the Netherlands, the National Centre in HIV Epidemiology and Clinical Research (NCHECR) in Australia and the Thai Red Cross AIDS Research Centre (TRC-ARC) in Bangkok, Thailand

transmission of HIV. The use of ROCHEPHIN® (ceftriaxone), which is also provided at reduced cost within the AAI programme, has a key role to play in the treatment of STDs.

4. In South Africa, a Roche-donated COBAS AMPLICOR[®] benchtop analyser to a leading medical research institute has increased local capacity and expertise. Patients in the local community are now benefiting from the centre's enhanced ability directly through the public health system and further private funding is secured from pharmaceutical clinical trials. Roche has also recently been appointed with the supply contract for screening of donor blood in South Africa. The programme is critical for reducing the transmission of HIV through blood products.
5. Roche provides resource and is involved in many children's programmes including support and education for **extra HIV-treating physicians** in paediatric clinics in South Africa and funding for the care of orphaned children and infected children and their families in the US, Thailand and Eastern Europe. Roche currently provides free DNA PCR diagnostic kits for clinical studies investigating mother-to-child transmission in Thailand, Uganda, Tanzania, Zimbabwe, Botswana and South Africa, and is a sponsor of the Cotlands Baby Sanctuary and CHANCE (Children's Home And Nurturing Centre), supporting children living with HIV/AIDS in South Africa.

- **Increased affordability**

Roche is committed to providing HIV medication to countries in sub-Saharan Africa and the 48 Least Developed Countries (LDC) at sustainable reduced prices **and has pledged not to profit from its HIV therapeutic portfolio in these countries.** Roche will continue to remain flexible and offer other developing countries affordable medicines with price reductions negotiated on a case by case basis taking into account the scale of the programme and drug requirement.

Roche does not believe that issues limiting access to HIV care in the LDCs will be solved by drug price reductions alone and is consequently working with third parties such as PAI to put infrastructures in place and encourage other international donors to invest in LDC novel initiatives

Roche's income from sales of HIV medications outside the LDCs will continue to contribute towards:

- Further improving access to HIV/AIDS drugs
- Provision of practical and financial assistance for Roche's **BlueSky Global Initiatives in Caring** programme
- Investment in developing novel strategies for more cost-effective use of current HIV medications.
- Funding global research programmes in the search for new HIV/AIDS treatment and diagnostic technology.

Merck & Co., Inc

Merck & Co., Inc.^{**} is committed to improving access to HIV/AIDS care and treatment in developing countries. Our primary role will continue to be a focus on the discovery and development of new medicines and vaccines. Merck also has an important role to play through public/private partnerships to bring new resources and expertise to bear in facilitating accelerated access to HIV/AIDS care and treatment and fostering health infrastructure development in those countries most directly affected by the HIV pandemic. Merck is involved in several significant initiatives in this respect:

- **UN/Industry Accelerating Access Initiative (AAI):** Merck has made a strong commitment to participation in the AAI, working closely with UNAIDS and other UN

^{**} Merck & Co., Inc., Whitehouse Station, NJ, USA, is known in most markets outside the US as Merck Sharp & Dohme (MSD).

agencies to respond to the particular needs of different countries, in a way and at a pace that makes sense to the country officials who have primary responsibility for the health of their populations. Merck has made its antiretrovirals available at significant discounts in all countries that have reached agreement with UNAIDS on expanding access to antiretroviral therapy as part of their HIV/AIDS strategy to date.

- **New HIV pricing policy for developing countries:** Merck announced on March 7, 2001, a decision to lower the prices of CRIXIVAN and STOCRIN in developing countries, to USD \$600 and USD \$500 per patient per year, respectively. At these prices, Merck will not profit from the sale of these medicines in the developing world. The offer extends not only to governments, but also to other stakeholders responsible for care and treatment, including NGO's, charitable organizations, and private sector employers.
- The lowest prices are available to all countries in the low category of the UNDP Human Development Index (HDI), as well as to those medium HDI countries with an adult HIV prevalence (as reported by UNAIDS) of 1% or greater – a total of some **60 countries** worldwide. (Medium HDI countries with an adult HIV prevalence of less than 1% have been offered prices of USD \$1029 per patient per year for CRIXIVAN and USD \$920 for STOCRIN. This offer extends to an **additional 52 countries**. High HDI countries are dealt with on a case-by-case basis; Chile, for instance, has been offered a 50% discount within the AAI.) The goal is to catalyze efforts to accelerate access - recognizing that lowering the price of medicines alone will not eliminate all barriers to care and treatment.
- To date, the following **43 countries** have accepted Merck's offer or product has already been shipped (this list includes AAI countries, in bold italics):

Africa:

Benin, Burkina Faso, Burundi, Cameroon, Central African Republic, Chad, **Congo, Côte d'Ivoire, Gabon**, Guinea (Conakry), Kenya, Malawi, **Mali, Morocco, Rwanda, Senegal**, South Africa, Swaziland, Tanzania, Togo, **Uganda**, Zambia, Zimbabwe.

Latin America:

Brazil, Colombia, **Chile**, Costa Rica, Ecuador, El Salvador, Guatemala, Haiti, Honduras, Jamaica, Mexico, Nicaragua, Panama, Peru, **Trinidad & Tobago**, Venezuela

Asia/Pacific:

Cambodia, Malaysia, Thailand

Eastern Europe:

Romania

- **Botswana Comprehensive HIV/AIDS Partnership:** In July 2000, the Republic of Botswana, The Bill & Melinda Gates Foundation and Merck began an ambitious, country-led programme designed to significantly improve Botswana's response to the HIV/AIDS epidemic across the entire spectrum of prevention, education, care, and treatment. The goal of the project is to demonstrate the feasibility of a targeted, comprehensive approach, from which lessons learned can be applied in other countries and similar contexts, with support from other donors. The Gates Foundation and Merck have each committed cash contributions of \$50 million over five years. In addition, Merck will supply at no charge to the government of Botswana whatever is required in the way of Merck's antiretrovirals, CRIXIVAN and STOCRIN. Other partners in the project include Boehringer-Ingelheim, Unilever PLC and the Harvard AIDS Institute, and discussions are under way with other potential partners.

Additionally, various short-term priorities have been identified, including increasing the capacity of laboratories nationwide; training programmes for health workers; assessment of medical stores and ways to enhance distribution and infrastructure; condom distribution; improving the effectiveness of voluntary testing and counseling programmes and referral to care nationwide; small grants to scale-up community-based initiatives; and a distance learning initiative to train teachers about HIV/AIDS. The Government of

Botswana has also announced plans to scale up care and antiretroviral treatment to reach 10,000 people by the end of 2001, which will be supported by the Partnership.

All activities are being conducted in close collaboration with the National Coordinating AIDS Agency, the Ministry of Health, and other key stakeholders in Botswana.

- **Enhancing Care Initiative (ECI):** This programme -- begun in 1998 and managed by local AIDS Care Teams, the Harvard AIDS Institute, and the Francois-Xavier Bagnoud Center -- is a multidisciplinary, multinational collaboration to enhance the care of men, women and children living with HIV/AIDS in resource-scarce countries. The goal of the ECI is to define the best means to deliver HIV/AIDS care-- in ways that are pragmatic, country-led and tailored to specific needs, recognizing that one size does not fit all. The projects evaluate needs, propose feasible/cost-effective improvements; evaluate and consider epidemiology/clinical science, scenario planning/economics, and human rights, and develop strategies and policy recommendations to effect changes in the countries -- with lessons applicable in other settings worldwide. Currently teams are active in Brazil, Senegal, South Africa (Kwa Zulu Natal province), Thailand and Puerto Rico.

Pfizer

In December 2000, Pfizer announced a programme in partnership with the Ministry of Health of South Africa to enhance access to care and treatment for low-income AIDS patients suffering from cryptococcal meningitis and esophageal candidiasis, two opportunistic infections commonly associated with AIDS. In addition to donating its anti-fungal, Diflucan®, Pfizer is funding a local NGO -- the HIV Clinicians Society/IAPAC -- to train physicians in secondary and tertiary care hospitals in latest advances in the treatment of AIDS-related opportunistic infections. By the end of this summer, over 6,000 patients had already been treated in all nine provinces, and more than 3,000 health care providers have been trained -- and both of these numbers continue to grow.

Given its initial success, the programme is expected to continue for an indefinite period of time. In early June 2001, Pfizer announced its commitment to expand the Diflucan Partnership Programme beyond South Africa. Using the UN's list of least developed countries as a guide, Pfizer has expanded the initiative into many of the world's poorest countries most in need and into several southern African countries. This donation has no time or cost limitation and will result in Diflucan being made available, free of charge, to those countries most in need.

In addition to the provision of treatment, the programme seeks to enhance local capacity to manage HIV/AIDS related illnesses through training of health care professionals. In addition to product donations through the company, Pfizer and the Pfizer Foundation announced two major grants to support AIDS work in Uganda that will help to build infrastructure and to disseminate best practices. The first grant was awarded to a new organization, The Academic Alliance for AIDS Care, Treatment and Prevention, being spearheaded by leading ID experts in the US, Canada and Uganda. The group is building a training and care center at Makerere University and plans to train 80 health care providers per year in the latest techniques in HIV/AIDS diagnosis, treatment and prevention. The trainees are then expected to return to their communities and train others. In addition, the center plans to treat up to 50,000 patients per year when fully operational. Pfizer Inc and the Pfizer Foundation are projected to invest up to \$11 million during the development and start-up of this programme. The second grant, \$315,000 through the Pfizer Foundation, is to support a study led by UNAIDS, the Uganda AIDS Commission and UNICEF to identify community-based initiatives/best practices that have helped reduce HIV/AIDS prevalence rates in Uganda. Study results will be used in Uganda and other countries to help guide AIDS policy, strategy and programme development moving forward.

Impact

The impact of accelerating access should be assessed against the broad principles embodied in the Statement of Intent, as set out above. As a result of the momentum of accelerating access, many developing countries are devising comprehensive and long-term strategies for HIV/AIDS prevention, care and treatment. They have produced national strategies and plans that lay the foundation for sound and sustainable solutions. This is a painstaking and at times a frustrating process. On the other hand, it engenders collaboration among stakeholders committed to achieving tangible results and has established new forms of public/private partnership.

The information about the numbers of new patients treated with antiretrovirals as a result of accelerating access indicates that, while some progress has been made in some countries, it has not yet been able to deliver against the expectations generated. Over the two to five year planning horizon of twelve of the countries involved in agreements so far, the number of people living with HIV/AIDS who will have access to antiretrovirals over present access levels is forecast to be 30,900 (from a baseline of 6,500). The three middle income countries that have reached agreement with the pharmaceutical companies (Chile, Morocco and Romania) and Gabon, in sub-Saharan Africa, have committed to *universal* access to antiretrovirals for people living with HIV/AIDS. In the least developed countries, the costs of reduced price antiretrovirals are still high relative to income.

It can be argued that middle income countries have benefited most from the price reductions achieved to date, given their lower incidence of HIV infection and higher per capita incomes (eg with an HIV infection rate of 1.5%, universal access in Chile would cost 0.5% of GDP, compared with 17% in some sub-Saharan African countries).

The relatively limited impact of accelerating access on increasing the number of new patients treated can be explained by several factors, including:

- concern within the initiative to introduce antiretrovirals in a responsible manner, in the context of a comprehensive approach to care, in a way that would not jeopardise their use in future (through the avoidance of drug resistance);
- the need to ensure that reduced prices in the south do not constitute a threat to market prices in the north, and therefore to preserve the viability of antiretroviral drug development worldwide;
- the limited capacity of participating countries to rationally use the drugs and control their distribution; and
- limited funding, especially in countries where per capita health spending may be as little at US\$2.00 to \$20.00 a year – not enough to purchase even one month's therapy at currently feasible prices.

Accelerating access has had a positive impact on the know-how of caregivers with regard to the use of antiretrovirals. The national care and treatment plans serving as a collaboration tool with the pharmaceutical companies have a strong capacity-building component, including the training of caregivers. This element of the plan is essential to the avoidance of drug resistance.

The encouragement of a regional approach has served to promote networking among countries. This should have a positive impact on other elements of the global response to the HIV/AIDS epidemic.

As part of the Country Response Information System that will be launched by the UNAIDS Secretariat in collaboration with WHO towards the end of 2001, accurate data on the quality and impact of expanded treatment programmes will become available.

Constraints on increased access

Two main factors contributing to the low uptake of low-price antiretrovirals, despite the evident interest from so many countries, are limited infrastructure for managing patient care and for providing laboratory support, and limited funding to cover the cost of the drugs, laboratory reagents and other commodities. The lack of infrastructure and trained personnel in developing countries, the uncertain and inadequate finance for the total cost of care in the

most affected countries, the reluctance to fund antiretroviral purchase on the part of many national governments and donors, and price levels that remain out of the reach of many developing country budgets mean that companies have not been able to report significant movement of products at this stage. There are high expectations that the Global AIDS and Health Fund will vastly increase the level of resources available to support a broad care agenda, including antiretrovirals.

Other constraints on scaling up access to HIV care in developing countries include uncertainty about the safest and most cost effective treatment regimens and difficulties with the establishment of safe, secure and effective procurement mechanisms.

Suggested areas for intensified joint action

The UN and the research-based pharmaceutical industry should work together more intensively to address these constraints and to increase the impact of initiatives on accelerated access to HIV care and support.

I. **Global AIDS and Health Fund** – there is considerable interest in increasing the resources available for HIV/AIDS care and support, including funding for the purchase of needed medicines. The transitional phase of the establishment of the Global AIDS and Health Fund, when the scope, shape and purpose of the Fund are being determined, provides the opportunity to pursue this. The leading role of pharmaceutical companies in the business community can help encourage private sector involvement, leading to a more effective global response.

II. **Regional perspectives and care initiatives within countries** – active support of regional initiatives to collaborate on improved access to care, along with further extension of discounted prices to accredited private sector and not-for-profit care providers and greater activity in middle income countries would serve to increase the impact of accelerated access more quickly.

III. **Infrastructure development and training** – increased participation of the private sector alongside UN technical agencies in the development of health care infrastructure, including support for human resources development, improved laboratory and diagnostic facilities and quality control measures, could help provide better care for people with HIV.

IV. **Operational and clinical research agenda** – greater sharing of ideas between the UN system and the private sector on an appropriate research agenda and better mechanisms for communication of research in progress, with a particular emphasis on optimal care regimens for resource-poor settings and optimal approaches to monitoring effectiveness and safety, could increase the effectiveness of investment in research and development. The UN and industry should continue to ensure a positive legal, trade and commercial framework is in place to encourage more intensive and broader investment in biological and medicinal product research and development for diseases primarily affecting the developing world.

AMSTERDAM STATEMENT

THE SECRETARY-GENERAL

Statement after meeting the leaders of six leading research-based
pharmaceutical companies

Amsterdam, 5 April 2001

I met today in Amsterdam with the top executives from six leading multinational pharmaceutical companies, along with Dr. Gro Harlem Brundtland, Director-General of the World Health Organization, and Dr. Peter Piot, Executive Director of UNAIDS, to discuss what further steps can be taken by these companies to make care and treatment more accessible for people living with HIV/AIDS in developing countries.

The way we have dealt with the needs of the developing world in recent years is simply not adequate. We need a radically different approach, and all sectors of society must be involved.

I called for this meeting because encouraging the active participation of all partners in the fight against AIDS has become my personal priority. The epidemic is the greatest public health challenge of our times and we must harness the expertise of all sectors of society. The pharmaceutical industry is playing a crucial role. I would also want to applaud the contributions by non-governmental organizations, who are our vital partners in this fight. We need to combine incentive for research with access to medication for the poor.

Intellectual property protection is key to bringing forward new medicines, vaccines and diagnostics urgently needed for the health of the world's poorest people. The UN fully supports the TRIPS agreement -- including the safeguards incorporated within it.

However, the solution does not lie with the pharmaceutical companies alone. I am calling for a major mobilisation -- of political will and significant additional funding -- to enable a dramatic leap forward in prevention, education, care and treatment.

I am pleased to tell you that the companies have today agreed to do the following:

First, to continue and accelerate reducing prices substantially, with a special emphasis on the Least Development Countries, particularly those in Africa.

Second, to continue to offer affordable medicines to other developing countries, on a country by country basis.

Third, to recognize the need to consider increased access to HIV/AIDS medicine to qualified non-governmental organizations and appropriate private companies offering health care to employees and local communities in these nations.

Today's commitments consolidate, and go beyond, the progress which individual companies had made in reducing prices since last May, when five of them signed a Joint Statement of Intent with the United Nations. This represents a contribution to the global response to the epidemic, going much further than any of us could have predicted twelve months ago.

At the same time, we must not forget that the price of drugs is only one of the issues that has to be addressed in improving the quality of care and treatment for HIV/AIDS affected people in the developing world. Drugs can only work if they form part of a comprehensive approach, which runs from voluntary counseling and testing to home and community-based care, and simple treatments for opportunistic infections. And, of course, our highest priority must still be to ensure that fewer people become infected with HIV in the first place.

None of these things can be achieved without spending a lot more money. IN the next few months, leading up to the Special Session of the General Assembly at the end of June, the United Nations will be working overtime to mobilise increased resources for all aspects of the struggle against HIV/AIDS, and for better health care in developing countries.

ACCELERATING ACCESS TO HIV/AIDS CARE, TREATMENT AND SUPPORT*

PROGRESS SEPTEMBER 2001

Background

Accelerating access emerged out of the partnership initiated in May 2000 between the UN (UNFPA, UNICEF, WHO, the World Bank and UNAIDS Secretariat,) and five pharmaceutical companies (Boehringer Ingelheim GmbH, Bristol-Myers Squibb, GlaxoSmithKline, Merck & Co., Inc., and F. Hoffmann-La Roche Ltd) to increase access to HIV/AIDS care, treatment and support.

As set out in the May 2000 Joint Statement of Intent, the UN/industry partnership was based on a set of broad principles, as follows:

- (i) unequivocal and ongoing political commitment by national governments
- (ii) strengthened national capacity
- (iii) engagement of all sectors of national society and the global community
- (iv) efficient, reliable and secure distribution systems
- (v) significant additional funding from new national and international sources
- (vi) continued investment in research and development by the pharmaceutical industry

Accelerating access has involved dialogue between the UN and the pharmaceutical industry to make quality drugs more affordable in developing countries, technical collaboration with countries in the development of national programme capacity to deliver care, treatment and support as well as consultation with governments and NGOs through a Contact Group.

While this is a collaborative process, legal obligations require the companies to continue to act individually and independently, particularly involving matters relating to the discovery, development and commercialization of products for the treatment or prevention of HIV/AIDS and related opportunistic infections.

Progress

UN/industry partnership

Abbott Laboratories and Pfizer Inc., together with four of the five companies signing the Joint Statement of Intent in May 2000 (Merck did not attend) participated in the meeting in Amsterdam in April 2001 with the Secretary-General, called to discuss options for intensifying the joint UN/industry contribution to increase access to HIV medicines and treatments (final statements from this meeting are attached). A subsequent meeting in Geneva in July 2001 between UNAIDS Cosponsors and Secretariat and industry to discuss progress and future steps in accelerating access involved representation from all seven companies.

Since the Amsterdam meeting, the companies, acting individually, have adopted a number of approaches to expand access to health care. These include: (a) continued and accelerated initiatives to make HIV/AIDS-related drugs more affordable to developing countries, particularly in sub-Saharan Africa; (b) enhanced partnerships with qualified non-governmental organizations and appropriate private companies offering health care to employees and local communities; and (c) concerted efforts to provide the necessary training to local health practitioners. Lower prices for groups of Least Developed Countries have been agreed with some companies individually and there have been a number of initiatives by

* *Background paper prepared by UNAIDS Secretariat for meeting of United Nations Secretary-General with the Chief Executives of the seven leading research-based pharmaceutical companies, New York, 4 October 2001*

individual industry partners to broaden access in the private sector and shipments have been made at the lowest prices to a number of eligible countries.

There have also been initiatives undertaken to expand donation programmes – with no cost or time limitations – to eligible countries and NGOs. With respect to affordability, companies, acting individually, have made specific public offers to supply some products at no profit, below cost, or free to qualifying countries.

In addition to renewed efforts to expand affordable access to antiretrovirals and other HIV-related medicines, each of the companies has built on existing initiatives and implemented broader partnerships, working with a wide range of countries, NGOs and health care organizations in developing countries to improve access to HIV care and treatment. These programs include efforts to train health care professionals, to build health infrastructure and capacity, to strengthen the role of NGOs in the continuum of care and to implement interventions designed to prevent mother-to-child transmission of HIV and to treat other targeted populations

The Geneva meeting reviewed progress towards achieving the commitments made in Amsterdam and highlighted several areas for further attention, including the need for expanded financing and health system development, regional collaboration, and increased affordability of drugs and diagnostics. Industry indicated it would welcome broadening the partnership to include companies that market generic drugs consistent with international agreements. It was agreed that intellectual property protection is key to bringing forward urgently needed new medicines, vaccines and diagnostics and the companies continue their efforts to discover and develop these new technologies. It was also agreed that a more positive view of the partnership and its achievements should be portrayed. This could highlight examples of effective cooperation at country and global level. The companies have indicated that they must operate within the provisions of anti-trust legislation.

Progress at country level

By mid-September 2001, 71 countries had indicated their interest in collaborating with UNAIDS on access to care and support, comprising 40 countries in Africa, 24 in Latin America and the Caribbean, 4 in Europe and 3 in Asia. A list of countries is attached.

Twenty six (26) of these countries have completed or are in the advanced stages of developing national care and treatment plans, most on the basis of some technical collaboration with the UN.

With involvement from UNAIDS, thirteen (13) of these countries – Burkina Faso, Burundi, Cameroon, Chile, Cote d'Ivoire, Gabon, Mali, Morocco, Romania, Rwanda, Senegal, Trinidad and Tobago and Uganda - have reached agreement with manufacturers on significantly reduced drug prices in the context of national plans. Individual companies have reported reaching agreement with four additional countries in the context of their accelerating access initiatives – Benin, Chad, Congo (Brazzaville) and Democratic Republic of Congo.

Significant price reductions have been achieved on an expanded range of HIV/AIDS medicines. Prices that have been publicly announced for Least Developed Countries in sub-Saharan Africa are set out in the Table attached. For some drugs, prices are higher outside sub-Saharan Africa (eg Morocco), albeit at price levels much lower than those in industrialised or high human development index (HDI) countries.

Regional collaboration

Because the country by country process of consultation on national AIDS plans and agreement on implementing antiretroviral therapy (including pricing discussions with individual companies) has been relatively slow and resource intensive, consideration has been given to developing a regional approach to expand the benefits more rapidly, for example through the possibility of bulk purchasing, shared technical assistance and joint resourcing. Regional initiatives, involving the development of regional plans for care, treatment and support, are

well under way in the Caribbean, Western and Southern Africa, and a first regional meeting on access is to be held this year in Southeast Asia. The UN is facilitating these efforts. Companies have indicated that they are comfortable with the concept of regional procurement, although principles and processes need to be explored further.

Recent UN actions

Assistance to countries

UNAIDS (Secretariat and Cosponsors) has been actively involved in facilitating greater access to care and treatment, assisting countries and governments identify options to increase care and support and supporting countries in the implementation of their chosen options. The number of countries seeking this support has doubled in a short period, from 35 in early May to over 70 now. Recent support for regional and sub-regional collaborations in part explains this rapid growth. A network of some 60 consultants from African and American countries, covering various disciplines, has been appointed and trained to speed up the process of country support. In providing assistance to countries, the UN continues to press its broad objective, to enhance progressively the capacity of countries to increase access to, and use of, sustainable, comprehensive and quality HIV/AIDS interventions across the entire spectrum of prevention, treatment, and patient care and support, including prevention of perinatal transmission.

Consistent with its mandate for advocacy and facilitation, UNAIDS has also been involved in mobilizing the vastly increased resources needed for care and treatment, in particular supporting consultations on the establishment of the Global AIDS and Health Fund and encouraging the flow of debt relief funds towards HIV/AIDS prevention and care programmes.

The World Bank's Multi Country HIV/AIDS Prevention and Control Programme (MAP) has recently approved a package of IBRD loans and IDA grants for several Caribbean countries and has agreed that, under certain conditions, parts of these loans may be assigned to the purchase of antiretroviral drugs. Barbados has been the first country fulfilling these conditions and therefore able to draw on World Bank loan funds to finance access to antiretrovirals. While MAP Phase I objectives in Africa cover capacity building for HIV/AIDS activities, including the infrastructure to facilitate access to treatment, MAP Phase II will more directly address access in selected countries.

Prevention of mother to child transmission

UNICEF is a key partner in UN efforts to implement programmes for the prevention of mother to child transmission of HIV/AIDS (PMCT). Such programmes are becoming more possible in resource poor settings with price reductions and donations of antiretroviral drugs. Programmes are now fully operational at 79 sites and in two national programmes in 16 countries, in Africa, Asia, Central and Eastern Europe and Latin America. Since the beginning of the pilot phase in Botswana and Rwanda in April 1999 up to July 2001, globally over 300,000 women have been reached, 220,000 have been counselled, 138,000 have been HIV tested and out of the 11,400 HIV positive mothers identified, over 4,500 have received antiretroviral therapy.

There is scope for improving provision of care and treatment so that more women with the potential to benefit have access to these interventions. There is also growing interest in offering "no test" Nevirapine to women whose HIV status is unknown at the time of delivery. HIV testing can be offered postpartum when it is particularly important to inform infant feeding choices. Recognising that women may be reluctant to be tested, PMCT Plus has emerged, proposing to provide women and mothers with ongoing care that may include antiretrovirals for the mother. One of the key issues in making such efforts feasible will be the training of health care workers in the care of HIV positive mothers, an effort where collaboration with the pharmaceutical industry may not only improve care delivery but assist in ensuring proper use of donated and price reduced antiretrovirals.

Tools and guidance

In May 2001, WHO convened a consultative meeting on the use of antiretroviral drugs in resource limited settings. Representatives from the pharmaceutical industry were not invited to participate in this discussion. Following this meeting, two technical working groups have been formed which are working on the development of simplified ARV treatment guidelines and the creation of a surveillance network for ARV drug resistance.

Current pricing information and data on suppliers is publicly available in "*Sources and prices of selected drugs and diagnostics for people living with HIV/AIDS*", a document produced by WHO, UNICEF, the UNAIDS Secretariat and MSF in June 2001. As the document points out, there are some limitations on the information provided in the report, which draws attention to the importance of quality assurance for pharmaceutical products.

In the context of dramatically increasing access to and affordability of HIV/AIDS related care and treatment, WHO, UNICEF, UNAIDS and UNFPA, supported by the World Bank, recently issued a second invitation to manufacturers of pharmaceutical products for the management of HIV-related diseases, to submit product dossiers for various dosages and strengths of the products in categories listed on the UNICEF Supply Division website.

Other WHO initiatives which serve to reinforce efforts to increase access to quality HIV/AIDS care, treatment and support include the production of a practical guide on the use of Nevirapine in the prevention of mother to child transmission and, in association with UNAIDS, UNFPA, UNICEF and the World Bank, a major project on pre-qualification, designed to ensure the pre-qualification of suppliers of HIV/AIDS related pharmaceutical products, to set up a model quality assurance system for procurement of pharmaceuticals, and to set out guidelines on the quality of pharmaceutical products related to HIV/AIDS. A joint WHO/WTO workshop on differential pricing in April 2001 explored the conditions required to bring into effect differential pricing for essential drugs. Further work on this is being pursued in collaboration with the TRIPS Council of the WTO.

Recent industry initiatives

Abbott Laboratories

Abbott Laboratories is committed to addressing the multi-faceted HIV/AIDS pandemic on multiple fronts. This commitment includes programmes that broaden access to therapy and assist those most directly affected by HIV/AIDS. Abbott research has led to the development of two widely prescribed protease inhibitors and numerous diagnostic products for HIV detection and therapy monitoring. While research remains a primary objective, Abbott Laboratories has also embarked on programs to broaden access to HIV care and testing and a major philanthropic endeavor related to HIV/AIDS.

? **Abbott Access:** Abbott Laboratories has strengthened its commitment to provide two therapeutic products (Norvir and Kaletra) and a diagnostic test (Determine HIV) at no profit. The initial offering for nations in Africa has been extended to include the 50 least developed countries, as defined by the UN. The application process to receive discounted product under this initiative is managed by Axios International, a consultancy specializing in health care in the developing world. Abbott Access is extended to entities that can utilize the products as part of sound and sustainable healthcare programmes, such as governments, NGOs, United Nations organizations, other national and international health institutions, private employers, hospitals, clinics, and other providers. Organizations that have successfully completed the application process are now receiving products at substantial discounts to support programmes that broaden access to HIV/AIDS care and treatment.

? **Tanzanian Drug Access Initiative.** Abbott has made a special commitment to the United Republic of Tanzania to strengthen its capabilities in dealing with the problems of HIV/AIDS. In June 2001, the Abbott Laboratories Fund sponsored a workshop to assist the Ministry of Health in the development of its HIV/AIDS action plan. Abbott is committed to

helping Tanzania develop a comprehensive programme for HIV diagnosis, care, treatment and support. Programme support will include technical assistance, certain product donations and the provision of products through the Abbott Access initiative.

? Step Forward[†]: In June 2000 Abbott initiated the Step Forward programme, a philanthropic initiative to assist AIDS orphans and vulnerable children in developing nations deeply affected by the pandemic. Step Forward programmes have broad flexibility to provide support in the areas of healthcare, voluntary counseling and testing, education and basic needs. Financial support, healthcare products and human resources are employed to construct or strengthen new or existing programmes. In Tanzania, among other activities, Step Forward has utilized employee-volunteers to strengthen laboratory infrastructure as it seeks to extend the reach of voluntary counseling and testing programmes in a remote region of the country. In Burkina Faso and India Step Forward assists the International HIV/AIDS Alliance in programmes related to health services at pre-schools, income generating activities and the linking of social service organizations with prevention and care programmes. In recent months, Step Forward has funded the renovation of a building that has become the Romanian-American Children's Center in Constanta through its partnership with Baylor University. As part of this programme Abbott is donating its antiretroviral therapies to as many as 500 children in that community. Renovation of the children's ward at Constanta Municipal Hospital and the purchase and renovation of a family home for abandoned children living with HIV/AIDS have also been completed.

Bristol-Myers Squibb

The mission of Bristol-Myers Squibb, a world leader in pharmaceutical development and infectious disease research, is to extend and enhance human life. The worldwide HIV/AIDS epidemic is a major area of focus for the Company. Besides the marketing of two anti-HIV therapies, VIDEX[®] (didanosine) and ZERIT[®] (stavudine), which are members of the class of antiretrovirals known as non-nucleoside reverse transcriptase inhibitors that form the backbone of Highly Active AntiRetroviral Therapy (HAART), Bristol-Myers Squibb is conducting an ambitious research programme identifying and developing new classes of anti-HIV drugs as well as investigating ways to make its current therapies simpler and more tolerable for people with HIV.

Drug discovery and development of medicines are only two parts of the company's commitment to solving the global HIV/AIDS crisis. Around the world, Bristol-Myers Squibb is supporting innovative programmes and outreach to those communities most devastated by the disease.

Secure the Future

In 1999, Bristol-Myers Squibb pledged an unprecedented \$100 million over 5 years to address the HIV/AIDS epidemic in the countries of South Africa, Namibia, Lesotho, Swaziland and Botswana through a programme called Secure the Future: Care and Support for Women and Children with HIV/AIDS. In 2001, an additional \$15 million was pledged to the West African nations of Senegal, Cote d'Ivoire, Mali and Burkina Faso. The largest corporate commitment to date, Secure The Future has two components: one involving Medical Research grants provided through the Bristol-Myers Squibb Pharmaceutical Research Institute which seek to support innovative, therapeutic research by local scientists and doctors to increase the capacity of the countries to manage the epidemic, and the other focusing on Community Outreach and Education grants provided by the Bristol-Myers Squibb Foundation, which help communities more effectively assist people living with HIV/AIDS by building on existing resources or expand or improve upon existing efforts to work against HIV/AIDS and its social consequences.

[†] The Step Forward program is an initiative of Abbott Laboratories and a philanthropic arm of the company known as the Abbott Laboratories Fund.

The Secure the Future initiative seeks to develop local capacity that will allow local organizations and individuals to address the HIV/AIDS epidemic in a sustainable way. To date, Secure the Future has approved 68 grants totaling over \$50 million in committed funds. A few examples of Secure the Future projects are:

Medical Research Grants

- In Botswana, Secure the Future partnered with the national government and the Harvard AIDS Institute to create a technologically advanced laboratory on the grounds of the country's biggest hospital, the Princess Marina Hospital. The laboratory's projects include: skills transfer and capacity development, the improvement of tools for monitoring HIV/AIDS, the first large-scale research study of antiretroviral therapy to treat AIDS and HIV infection in Botswana, assessment of resistance depending on regimen and adherence strategy and research on a possible vaccine.
- Investigating an improved and cost-effective alternative approach for the generation of CD4 cell counts to monitor response to HIV/AIDS therapy, Secure the Future provided a grant to the South African Institute for Medical Research at the University of Witwatersrand in South Africa. Results from this project have identified a more cost effective and accurate method to enumerate CD4 cells, with less technological expertise needed, which may prove highly valuable in resource-limited settings.
- At the Chris Hani Baragwanath Hospital in Soweto, South Africa, reportedly the largest in the world, a grant from Secure the Future to the hospital's Perinatal HIV Research Unit is enrolling willing women who did not receive antiretroviral treatment during pregnancy or delivery and women who were diagnosed as being HIV infected post-delivery in a study to see whether a postpartum treatment regimen for the babies can be effective in preventing their infection by the HIV/AIDS virus.
- Students at nursing colleges across the sub-Saharan region will be studying the management of HIV/AIDS by way of a new curriculum developed with the support of a Secure the Future grant and Baylor College of Medicine. The curriculum, which is being translated into French, covers a broad spectrum of areas needed to understand the complexities of HIV/AIDS management, such as epidemiology, pathophysiology, testing and counseling, antiretroviral treatment and psychosocial, legal and ethical issues. Nursing associations from across Africa have expressed interest in using the curriculum for the training of nurses in their countries.

Community Outreach and Education

- Secure the Future has supported a two-year master's programme in HIV/AIDS policy at the School of Public Health at the Medical University of Southern Africa (MEDUNSA). To date, more than 100 people are enrolled in the programme, many of whom are already playing key roles in formulating their countries' and their communities' policies on dealing with the epidemic.
- In Swaziland, the fund is helping to mobilize local non-governmental organizations by supporting an eight-module training programme to build the organizations' capacity to deal with HIV/AIDS-related projects. In May 2001, 80 organization members, including pastors in church-based efforts and youth activists, received certificates from the Institute.
- Also in Swaziland, the fund, in partnership with Cabrini Mission Foundation, has helped support training in home-based care dealing with HIV/AIDS for a cadre of 2,500 community health workers known as Rural Health Motivators who represent the backbone of that country's health care system. This group works against the stigma associated with HIV/AIDS that has prevented many community residents from seeking treatment.
- Secure the Future has also helped support the Reetsanang Association of Community Drama Groups, a Botswanan organization that travels across the country especially to marginalized and remote rural areas, conducting participatory HIV/AIDS education workshops and interactive theater performances that air community issues. The goal of the programme is to destigmatize and mobilize through key HIV/AIDS intervention messages.
- In South Africa, Secure the Future is supporting the Bambisanani Project, an effort in three poverty-stricken rural areas in the Eastern Cape Province to provide an integrated

approach to support people living with HIV/AIDS and their families. The efforts include identifying and training community care supporters and primary caregivers at home, building drop-in centers to house support groups and income-generating activities and conducting a study of children in distress as a result of the disease.

- In Lesotho, a Secure the Future-funded grant supports a project in partnership with the Cooperative for Assistance and Relief Everywhere (CARE) addressing HIV/AIDS destigmatization through peer education and prevention tactics among women and children in the border towns of Lesotho and South Africa.
- Building a national lay counseling capacity in Northwest Namibia is the focus of another grant from Secure the Future. The project plan covers community consultations with key opinion leaders, traditional leaders, community-based organizations, women's organizations and government, as well as the training of community-based lay counselors and volunteers,

Thailand

The Thai Red Cross, with the support of the Bristol-Myers Squibb Foundation, is preparing a multiyear effort to help children living in slum communities acquire skills they can use to protect themselves against HIV/AIDS. In Bangkok, there are roughly 300,000 children living in such communities, where the children are highly exposed to the AIDS virus through unprotected sex and sex with commercial sex workers. The AIDS Research Centre will train 500 children using a novel approach to behavior modification called life skills training. Life skills training involves the use of games, role playing and community theater to help participants gain skills in decision making, problem solving, critical thinking and communication. If the training programme proves successful, the Thai Red Cross hopes to extend it to other communities and to present it to the Thai Ministry of Health for possible use in national youth training.

Mexico

HIV/AIDS has created an urgent health crisis in Mexico, especially for the most vulnerable victims of the disease – children. Without access to lifesaving drugs or a comprehensive system for managing the disease, Mexican children with HIV/AIDS have faced a future of degradation, despair and early death. The Bristol-Myers Squibb Foundation has responded to this crisis by joining hands with the Hospital Infantil and other partners in Mexico to develop innovative programmes to treat children with AIDS as well as to help prevent the further spread of the disease. With training assistance from Baylor College of Medicine in Houston, TX, local medical facilities are being established or improved to better diagnose and treat the disease. Additionally, the Foundation-sponsored programme is educating women – particularly pregnant women and women of childbearing age – on prevention of HIV/AIDS, including the importance of screening. The aim is to break the cycle of infection that is threatening to make HIV/AIDS an even greater public health menace in Mexico. Finally, the programme helps bring lifesaving medicines to the children who need them so desperately.

UN/Industry Accelerating Access Initiative (AAI)

Bristol-Myers Squibb has been a strong participant in the AAI since its inception more than 18 months ago. The Company has worked closely with UNAIDS and the other public sector agencies involved in the AAI (UNICEF, the World Bank, the WHO and UNFPA) as well as with the governments in developing countries who have indicated a willingness and desire to work with the AAI in developing and implementing national plans to expand access to sustainable prevention, care and treatment of HIV/AIDS. As part of its commitment, Bristol-Myers Squibb has offered its two antiretroviral medications, *Videx* and *Zerit* at discounts of up to 93% from the prices offered in the USA and Europe to developing countries that have reached agreement with UNAIDS on ways to expand access to ARV's for their citizens.

- On March 14, 2001, Bristol-Myers Squibb announced that it would make *Videx* (didanosine) and *Zerit* (stavudine) available to countries in sub-Saharan Africa who were interested in implementing an expanded access to ARV programme in their country at a price that was below its costs. The combined price of *Videx* and *Zerit* would be \$1.00/day

(\$0.85 / day for 400mg of *Videx*; \$0.15 / day for 80mg of *Zerit*). To date, the following 12 sub-Saharan African country governments have availed themselves of BMS' offer:

- Benin, Burkina Faso, Burundi, Cameroon, Chad, Congo (Brazzaville), Côte d'Ivoire, Gabon, Mali, Rwanda, Senegal, Uganda
- In addition, this offer has been made available to any non-government organization, any charitable organization, any private-sector caregiver or to any private sector employer in sub-Saharan Africa able to deliver medically sound care and treatment all the while keeping the costs of this delivery as low as possible. *Videx* and *Zerit* are available in this way at \$1.00 / day in these additional 11 sub-Saharan African countries:
 - Botswana, Kenya, Lesotho, Malawi, Mozambique, Namibia, South Africa, Swaziland, Tanzania, Zambia, Zimbabwe
- Vastly reduced prices on *Videx* and *Zerit* are now available in these 3 non-sub-Saharan African countries:
 - Romania, Chile, Trinidad & Tobago
- Finally, on March 14, 2001, Bristol-Myers Squibb announced that it would ensure that its patents do not prevent inexpensive HIV/AIDS therapy in Africa.

Boehringer Ingelheim

In July 2000, Boehringer Ingelheim announced the VIRAMUNE® Donation Programme for the Prevention of Mother-to-Child Transmission of HIV-1. This programme represents the company's commitment to provide VIRAMUNE (nevirapine) free-of-charge for a period of five years to developing countries.

Boehringer Ingelheim, together with a third-party consultant, Axios International, has developed an application process that is designed to provide the confidence that the donated drug will reach the patients that it is intended to help. Applicants are strongly encouraged to use the donated drug in the context of a comprehensive mother-to-child transmission (MTCT) prevention programme, as is consistent with the recommendations of the UN family of agencies. Boehringer Ingelheim shares the vision of the UN that comprehensive MTCT prevention programmes, including the prophylactic use of antiretrovirals, will provide a sustained benefit for the affected community.

Following the initial announcement of Boehringer Ingelheim's commitment to donate VIRAMUNE, there were not an overwhelming number of requests from interested governments, NGOs and other health care providers to participate in the programme. In the past few months, however, the number of applicants has increased dramatically. Boehringer Ingelheim has now approved 19 applications from 12 countries in Africa and the Caribbean, for which the company have committed to deliver approximately 50,000 treatments. To-date, drug supplies have been delivered to treat approximately 20,000 mother-infant pairs in seven of these programmes. Plans are underway to deliver the remaining supplies in the near future. Unfortunately, the programme is still too early in its implementation to know precisely how many treatments have actually been used.

Based upon the experiences to-date, the lag time in receiving applications appears to have been related to the difficulties in many of these countries to provide access to the health care capacity necessary to use even this simple therapy in the context of a comprehensive MTCT prevention programme. As awareness and interest concerning the establishment of comprehensive programmes increased, so did the interest in the VIRAMUNE Donation Programme. The experience in the VIRAMUNE Donation Programme is likely to be analogous to that which will be seen in the broader area of access to antiretrovirals for chronic treatment; namely, significant expansion of access to these medicines will be preceded by interest and investment into the development of infrastructure and services that

generally increase access to health care. In short, expanding access to health care is a prerequisite to expanding access to medicines.

GlaxoSmithKline

GlaxoWellcome (GW) offered significantly discounted prices for Retrovir (AZT), Epivir (3TC), and Combivir (AZT/3TC) since 1997 for MTCT programmes in sub-Saharan Africa. SmithKline Beecham offered substantial discounts on vaccines to public health programmes since 1980.

In May 2000, GW expanded preferential pricing for those medicines in developing countries through the Accelerating Access Initiative. The AAI has also involved close partnership with our UN partners, especially UNAIDS, developing countries, and our other industry colleagues. This has contributed to real progress since the beginning of 2001.

On 11 June 2001 the newly-formed GlaxoSmithKline (GSK) announced a number of new commitments to address the challenge of HIV/AIDS and other diseases of the developing world. Many of these commitments were directly in line with the objectives set at the Amsterdam meeting in April 2001.

GSK's commitment is threefold: continuing our investment in the research and development of medicines and vaccines for diseases that affect the developing world in particularly; offering sustainable preferential pricing arrangements in Least Developed Countries and sub-Saharan Africa for currently available medicines needed most; and taking a leading role in community activities that promote effective healthcare. GSK's approach is underpinned by a series of key principles - sustainability, appropriate use, support for innovation, partnership, and shared responsibilities.

GSK's commitments are fully manifested in our activities on HIV/AIDS.

Commitment to Research

GSK is the only company currently involved in research and development for both prevention and treatment of all three top priority diseases of the World Health Organization: malaria, tuberculosis and HIV/AIDS.

In 2001, GSK's HIV candidate vaccine will move into clinical trials in the US Government's National Institutes of Health HIV Vaccine Trials Network. It is hoped this vaccine will be effective against clade B. We will also be developing an HIV vaccine for use internationally, targeting at least one other strain circulating in Africa and Asia. With regard to new treatments for HIV/AIDS, GSK has clinical projects under way with a new combination product and a novel protease inhibitor, as well as research efforts to discover medicines with novel mechanisms.

Sustainable Preferential Pricing

On June 11, GSK announced preferential pricing for its range of antiretrovirals and anti-malarials.

Expanded Range of HIV/AIDS Products for Preferential Pricing

The company already made three established HIV/AIDS medicines - Retrovir, Epivir and Combivir - available at up to a 90% discount from the world average price. GSK is now also offering its newer HIV/AIDS medicines at preferential prices. Those medicines are: Ziagen (abacavir) a nucleoside analogue; Trizivir, the first medicine to combine three nucleoside analogues in one tablet (Ziagen, Epivir and Retrovir) and Agenerase (amprenavir), a protease inhibitor. In all markets where GSK products are available, the company is working with governments and other partners to ensure its products are used appropriately and effectively by the patients for whom they are intended.

Expansion of Countries Eligible for Preferential Pricing Offers -

GSK is offering all of its HIV/AIDS medicines at preferential prices to all countries in Sub-Saharan Africa and all Least Developed Countries (LDC) as identified by the United Nations - a combined total of 63 countries. The prices available to these countries are fixed single prices and are not for profit.

The company's anti-retroviral medicines will also be available at discounted prices to other countries that join the Accelerating Access Initiative. GSK will also continue to work on a case-by-case basis with middle income developing countries to negotiate public sector prices that maximise affordability for governments in their treatment programmes.

Expansion of Customer Groups Eligible for Preferential Pricing Offers

GSK has extended its preferential pricing offer for HIV/AIDS medicines beyond Governments to include not-for-profit non-governmental organizations (NGOs), such as international agencies, aid groups, churches and charities that have the facilities in place to appropriately monitor and treat patients. In recognition of the gravity of the HIV/AIDS situation in Sub-Saharan Africa, GSK is offering preferential prices on anti-retroviral therapy to employers in Africa which offer HIV/AIDS care and treatment directly to their staff through their own workplace clinics. GSK has also extended its preferential pricing offer for HIV/AIDS medicines to include any international health funds that may be set up.

Plans to Develop a Pilot Programme to Assess the Impact of Preferentially Priced Treatments in Resource-Poor Settings

In addition to its anti-retrovirals and anti-malarials, GSK hopes to offer sustainable preferential prices for its anti-infective, de-worming diseases and anti-diarrhoeal products in the developing world. It is important that we test the sustainability of our proposals. Sustainability means that it is long term for the patient and commercially viable for GSK. GSK therefore hopes to undertake pilot projects in partnership with non-government organizations and various charities to assess the impact of comprehensive discounting arrangements in five African countries following discussion and agreement with each national government. The pilots will be evaluated to assess their success in expanding effective treatment of patients, programme modification needs, and potential for extending them to other countries.

Taking a Leading Role in Community Activities to combat HIV/AIDS

Positive Action

Positive Action is GSK's international programme of HIV education, care, and community support. Through the programme, GSK works in partnership with individuals, community groups, healthcare providers, governments, international agencies, and others in order to pursue the common goals of more effective HIV prevention, education, and enhanced care and support for people living with, or affected by HIV/AIDS. Since its inception in 1992, Positive Action has supported and implemented a wide variety of projects at both a national and international level, throughout the world.

UNICEF MTCT prevention programme

Since 1998, the company has been collaborating with UNICEF and UNAIDS on a UN-led international programme to provide MTCT in developing countries by providing the initial free start up supply of *Retrovir* (30,000 treatments or 2.5 million tablets). The programme has been extended from the original 11 countries to 25. The country programmes will then progress to access based on preferentially priced medicines.

GSK France Foundation

GSK France Foundation was started in August 1998 to improve prevention, education, training, and care in the area of infectious diseases. Current programmes aim to provide support in facilitating better access to care and treatment for people living with HIV in developing countries. 17 programmes are under way in 7 countries: Ivory Coast, Senegal, South Africa, Morocco, Cameroon, Mali, and Burkina Faso. The total number of people that will be affected by these programmes are 150,000 people (mainly women) via access to voluntary testing (VCT) and adequate antenatal care and 7,500 people (women, children, and men) via access to follow-up care.

Results

GSK has concluded preferential pricing arrangements with over 20 NGOs and private employers in Sub-Saharan Africa. Each of these entities has signed a Memorandum of Understanding (MOU) with GSK. Similar arrangements have been reached through the AAI with 13 countries and again, each of these countries have signed an MOU and supply agreement. GSK is in the process of working with numerous NGOs, private employers, and developing country governments and new MOUs are being signed weekly.

What is clear is that technical assistance, enhanced healthcare infrastructure, and sustainable financing are critical in any of these discussions. The challenge now is for the global community to meet the needs of NGOs, governments as they attempt sustainable and long-term care and treatment. This can only be achieved through partnership.

F. Hoffmann La-Roche Ltd

Roche is a company with a strong dedication to healthcare, our core being the discovery, development and provision of life-saving therapies and diagnostic tests to address the HIV epidemic. Roche believes that drug price is only one of the many barriers to care and that the building and sharing of knowledge at all levels is crucial to the prevention and management of HIV/AIDS. There is no simple or single solution that works for everyone and it is clear that no person, country, organization or company can hope to defeat HIV and AIDS alone. Instead, we all need to work together in a holistic way that addresses local community needs, to find the solutions that will make a difference to the lives of people living with HIV.

- **Research commitment**

In addition to the provision of a broad range of HIV treatments currently used in HIV and AIDS therapy, Roche invests significantly in HIV research and development.

- Roche's research effort is ongoing globally to **find better drugs, optimal regimens** to prolong the use of existing treatments, **improved formulations** and more **sensitive diagnostic tools (used to diagnose different strains and subtypes common in sub-Saharan Africa but rare in the developed world)**, to tackle the problem of rapid detection, early treatment, increased drug resistance and the challenges of adherence.
- Many people living with HIV are also infected with **hepatitis C** and Roche is currently developing a once-weekly, pegylated form of interferon, PEGASYS® (peginterferon alfa-2a) for the treatment of this condition. Similarly, coinfection with cytomegalovirus (CMV) can give rise to a severe eye disorder called CMV-retinitis. Roche provides Cymevene for the treatment of CMV-retinitis and is currently launching Valcyte, a pro-drug of oral ganciclovir that has significantly greater convenience than Cymevene and can be used in place of the i.v.- ganciclovir induction phase of treatment.
- HIV is an unforgiving virus and there is an urgent need to find new treatment options with a different mechanism of action and which are effective against **multi-drug resistant HIV virus**. In collaboration with Progenics Pharmaceuticals Inc., USA and Trimeris Inc., USA, Roche aims to discover and develop new generations of anti-HIV drugs. Together, Roche and Trimeris are investing approximately half a billion US dollars to bring the most clinically advanced of these, the **fusion inhibitors**, to those

people with HIV who most need them. Unlike traditional HIV/AIDS drugs, all of which work inside the already infected cell, fusion inhibitors attack HIV outside the cell thereby preventing fusion between the virus and the cell, the process that normally results in viral replication.

By combining its existing anti-HIV treatments and cutting-edge diagnostic technology with the potential of new research compounds, Roche is adopting an integrated approach to addressing the challenges of HIV and AIDS. In this way, Roche is committed to finding and delivering more effective long-term healthcare solutions to people living with HIV.

- **Partnership**

Collaboration is essential to the success of access programmes and Roche supports a variety of initiatives around the world designed to help build local capacity and resources to ensure long-term sustainable healthcare. Specific examples include:

1. In partnership with **PharmAccess International (PAI)**[‡], Roche is already taking the first step to widening access to HIV therapy in Africa, in a controlled, clinically sound and sustainable way by focussing on the improvement and build-up of the local medical infrastructure. The goal is to **expand access to HIV therapy** for HIV-1 infected patients in Côte d'Ivoire, Kenya, Senegal and Uganda. The provision of the latest treatments for HIV and opportunistic infections (that are common in Africa but rare in developed world countries), training of healthcare professionals and patient education are key elements of this partnership initiative.

PAI is providing its medical and logistical expertise implementing clinical programmes in developing countries and Roche is providing full financial support for the programme to cover the costs of antiretroviral drugs, diagnostic and monitoring testing, training of healthcare professionals and patient education. The PAI access programme will also benefit from Roche's support and technical expertise in the areas of patient education, HIV prevention and counselling programmes, and training of local healthcare professionals to ensure that they are equipped to deliver the highest standards of HIV-related care. Supported by a series of workshops involving counsellors, lab technicians, pharmacists and African physicians partnered with European Physicians, newly acquired skills and knowledge will be shared and the programme cascaded through additional centres and beyond.

The programme also aims to establish the use of a potent, once-daily and cost-effective protease inhibition treatment strategy under local conditions. The treatment regimen to be studied includes the use of Roche's protease inhibitor, FORTOVASE® (saquinavir) on a once-daily basis, combined with a 'boosting' dose of ritonavir and the nucleoside analogues AZT and 3TC. The aim of this therapeutic approach is to enhance the convenience of HAART regimens and to further reduce the cost of therapy.

The pilot programme with 100 physicians/ healthcare professionals trained is just a beginning and provides a framework for the future addition of more patients. It is truly a cross-cultural endeavour – the draft protocol has been reviewed by African, European and North American physicians and has been submitted for approval to STEG (the Dutch national ethics committee) in the Netherlands and also to the African countries. The programme will be rolled out in the next 6 months and Roche will send auditors to visit clinical centres to support and troubleshoot to ensure a successful implementation of the programme. **It is anticipated that the first of the 200 patients in the initial phase will be enrolled in the next 2 months.** The initial phase of the programme will run for two years, following which the participating patients will continue to receive the medication under the same conditions while the scope of the programme is expected to be expanded into other centres and countries with funding from other international donors.

The PAI's pilot cohort programme, CARE (Cohort programme to evaluate Access to anti-Retroviral therapy and Education), is designed to evaluate the effectiveness, safety and tolerability of a standard HAART regimen provided in 4 low-income settings to patients

[‡] PAI is a not-for-profit Dutch-American organization of independent healthcare professionals and is closely linked to the International Antiviral Therapy Evaluation centre (AMC-IATEC) at the Academic Medical Center in Amsterdam, The Netherlands

who would otherwise have no access to highly active antiretroviral therapy (HAART). In addition the cost-effectiveness of the therapy and the influence of patient disease education on compliance will be studied. An attempt will be made to evaluate the benefits of providing access to care on the quality-of-life of the patients, and on their ability to work. Health care personnel will be trained in order to give them an update of current international knowledge about HIV-management and to ensure that patients receive adequate medical care. The results of the pilot programme will be used to determine the feasibility of increasing access to antiretroviral therapy in developing countries. **The pilot has been designed so that every element can be amplified with the commitment and funding of other donors from the international community.**

2. Through its collaboration with **HIV-NAT[§]** in Thailand, Roche is focused on finding locally sustainable solutions that make a difference to the lives of people with HIV. The HIV-NAT clinical programme studies the efficacy and safety of different HIV treatment regimens under local conditions in Thai patients. The first study was completed in September 1996. The successful completion of the second study in 1997 attracted further interest and investment in the Centre and another nine trials are ongoing in Bangkok/Thailand sites with about 1,200 people with HIV now benefiting from effective treatment.

Through the help of supporters like Roche, the HIV-NAT programme is able to make drugs available to study participants and, through various schemes, continues to provide access to therapy beyond each study's completion. This commitment has ensured that all those involved with HIV-NAT trials are still benefiting from the most effective anti-HIV therapy.

Results from HIV-NAT research have recently been presented at an international HIV therapy workshop in the Netherlands in April 2001. The data provides further support for the investigational use of the soft gel capsule formulation of the protease inhibitor, FORTOVASE[®] (saquinavi), combined with a low booster dose of zidovudine to provide a potentially simplified and cost effective HIV treatment strategy.

Furthermore, Roche is donating saquinavir for 400 Thai patients in a structured therapy interruption (STI) study. The STACCATO study, to be conducted in Thailand, Australia, and Europe will look at the use of intermittent antiretroviral therapy to reduce costs of treatment as well as side effects.

HIV-NAT study results are shared with local HIV-treating physicians and Thai policy-makers and are also presented at international meetings. Results from HIV-NAT studies and those of international researchers were influential in the recent decision of the Ministry of Public Health (MOPH) to recommend triple antiretroviral therapy as standard of care in Thailand. This sharing of knowledge, combined with the increase in study-related income for those laboratories involved, is challenging and changing perceptions in Thailand about the treatment of HIV/AIDS and is further strengthening the country's HIV research and care infrastructure.

3. Roche has a long-standing involvement in the treatment of other sexually transmitted diseases (STDs). STDs are believed to constitute a confounding factor in the transmission of HIV. The use of ROCHEPHIN[®] (ceftriaxone), which is also provided at reduced cost within the AAI programme, has a key role to play in the treatment of STDs.
4. In South Africa, a Roche-donated **COBAS AMPLICOR[®] benchtop analyser** to a leading medical research institute has increased local capacity and expertise. Patients in the local community are now benefiting from the centre's enhanced ability directly through the public health system and further private funding is secured from pharmaceutical clinical trials. Roche has also recently been appointed with the supply contract for screening of donor blood in South Africa. The programme is critical for reducing the transmission of HIV through blood products.

[§] HIV-NAT is an international collaboration between the International Antiviral Therapy Evaluation Centre (IATEC) in the Netherlands, the National Centre in HIV Epidemiology and Clinical Research (NCHECR) in Australia and the Thai Red Cross AIDS Research Centre (TRC-ARC) in Bangkok, Thailand

5. Roche provides resource and is involved in many children's programmes including support and education for **extra HIV-treating physicians** in paediatric clinics in South Africa and funding for the care of orphaned children and infected children and their families in the US, Thailand and Eastern Europe. Roche currently provides free DNA PCR diagnostic kits for clinical studies investigating mother-to-child transmission in Thailand, Uganda, Tanzania, Zimbabwe, Botswana and South Africa, and is a sponsor of the Cotlands Baby Sanctuary and CHANCE (Children's Home And Nurturing Centre), supporting children living with HIV/AIDS in South Africa.

- **Increased affordability**

Roche is committed to providing HIV medication to countries in sub-Saharan Africa and the 48 Least Developed Countries (LDC) at sustainable reduced prices **and has pledged not to profit from its HIV therapeutic portfolio in these countries**. Roche will continue to remain flexible and offer other developing countries affordable medicines with price reductions negotiated on a case by case basis taking into account the scale of the programme and drug requirement.

Roche does not believe that issues limiting access to HIV care in the LDCs will be solved by drug price reductions alone and is consequently working with third parties such as PAI to put infrastructures in place and encourage other international donors to invest in LDC novel initiatives

Roche's income from sales of HIV medications outside the LDCs will continue to contribute towards:

- Further improving access to HIV/AIDS drugs
- Provision of practical and financial assistance for Roche's **BlueSky Global Initiatives in Caring** programme
- Investment in developing novel strategies for more cost-effective use of current HIV medications.
- Funding global research programmes in the search for new HIV/AIDS treatment and diagnostic technology.

Merck & Co., Inc

Merck & Co., Inc.^{**} is committed to improving access to HIV/AIDS care and treatment in developing countries. Our primary role will continue to be a focus on the discovery and development of new medicines and vaccines. Merck also has an important role to play through public/private partnerships to bring new resources and expertise to bear in facilitating accelerated access to HIV/AIDS care and treatment and fostering health infrastructure development in those countries most directly affected by the HIV pandemic. Merck is involved in several significant initiatives in this respect:

- **UN/Industry Accelerating Access Initiative (AAI)**: Merck has made a strong commitment to participation in the AAI, working closely with UNAIDS and other UN agencies to respond to the particular needs of different countries, in a way and at a pace that makes sense to the country officials who have primary responsibility for the health of their populations. Merck has made its antiretrovirals available at significant discounts in all countries that have reached agreement with UNAIDS on expanding access to antiretroviral therapy as part of their HIV/AIDS strategy to date.
- **New HIV pricing policy for developing countries**: Merck announced on March 7, 2001, a decision to lower the prices of CRIVAN and STOCRIN in developing countries, to USD \$600 and USD \$500 per patient per year, respectively. At these prices, Merck will not profit from the sale of these medicines in the developing world. The offer extends

^{**} Merck & Co., Inc., Whitehouse Station, NJ, USA, is known in most markets outside the US as Merck Sharp & Dohme (MSD).

not only to governments, but also to other stakeholders responsible for care and treatment, including NGO's, charitable organizations, and private sector employers.

- The lowest prices are available to all countries in the low category of the UNDP Human Development Index (HDI), as well as to those medium HDI countries with an adult HIV prevalence (as reported by UNAIDS) of 1% or greater – a total of some **60 countries** worldwide. (Medium HDI countries with an adult HIV prevalence of less than 1% have been offered prices of USD \$1029 per patient per year for CRIXIVAN and USD \$920 for STOCRIN. This offer extends to an **additional 52 countries**. High HDI countries are dealt with on a case-by-case basis; Chile, for instance, has been offered a 50% discount within the AAI.) The goal is to catalyze efforts to accelerate access - recognizing that lowering the price of medicines alone will not eliminate all barriers to care and treatment.
- To date, the following **43 countries** have accepted Merck's offer or product has already been shipped (this list includes AAI countries, in bold italics):

Africa:

Benin, Burkina Faso, Burundi, Cameroon, Central African Republic, Chad, **Congo, Côte d'Ivoire, Gabon**, Guinea (Conakry), Kenya, Malawi, **Mali, Morocco, Rwanda, Senegal**, South Africa, Swaziland, Tanzania, Togo, **Uganda**, Zambia, Zimbabwe.

Latin America:

Brazil, Colombia, **Chile**, Costa Rica, Ecuador, El Salvador, Guatemala, Haiti, Honduras, Jamaica, Mexico, Nicaragua, Panama, Peru, **Trinidad & Tobago**, Venezuela

Asia/Pacific:

Cambodia, Malaysia, Thailand

Eastern Europe:

Romania

- **Botswana Comprehensive HIV/AIDS Partnership:** In July 2000, the Republic of Botswana, The Bill & Melinda Gates Foundation and Merck began an ambitious, country-led programme designed to significantly improve Botswana's response to the HIV/AIDS epidemic across the entire spectrum of prevention, education, care, and treatment. The goal of the project is to demonstrate the feasibility of a targeted, comprehensive approach, from which lessons learned can be applied in other countries and similar contexts, with support from other donors. The Gates Foundation and Merck have each committed cash contributions of \$50 million over five years. In addition, Merck will supply at no charge to the government of Botswana whatever is required in the way of Merck's antiretrovirals, CRIXIVAN and STOCRIN. Other partners in the project include Boehringer-Ingelheim, Unilever PLC and the Harvard AIDS Institute, and discussions are under way with other potential partners.

Additionally, various short-term priorities have been identified, including increasing the capacity of laboratories nationwide; training programmes for health workers; assessment of medical stores and ways to enhance distribution and infrastructure; condom distribution; improving the effectiveness of voluntary testing and counseling programmes and referral to care nationwide; small grants to scale-up community-based initiatives; and a distance learning initiative to train teachers about HIV/AIDS. The Government of Botswana has also announced plans to scale up care and antiretroviral treatment to reach 10,000 people by the end of 2001, which will be supported by the Partnership.

All activities are being conducted in close collaboration with the National Coordinating AIDS Agency, the Ministry of Health, and other key stakeholders in Botswana.

- **Enhancing Care Initiative (ECI):** This programme -- begun in 1998 and managed by local AIDS Care Teams, the Harvard AIDS Institute, and the Francois-Xavier Bagnoud Center -- is a multidisciplinary, multinational collaboration to enhance the care of men, women and children living with HIV/AIDS in resource-scarce countries. The goal of the ECI is to define the best means to deliver HIV/AIDS care-- in ways that are pragmatic,

country-led and tailored to specific needs, recognizing that one size does not fit all. The projects evaluate needs, propose feasible/cost-effective improvements; evaluate and consider epidemiology/clinical science, scenario planning/economics, and human rights, and develop strategies and policy recommendations to effect changes – with lessons applicable in other settings worldwide. Currently teams are active in Brazil, Senegal, South Africa (Kwa Zulu Natal province), Thailand and Puerto Rico.

Pfizer

In December 2000, Pfizer announced a programme in partnership with the Ministry of Health of South Africa to enhance access to care and treatment for low-income AIDS patients suffering from cryptococcal meningitis and esophageal candidiasis, two opportunistic infections commonly associated with AIDS. In addition to donating its anti-fungal, Diflucan®, Pfizer is funding a local NGO -- the HIV Clinicians Society/IAPAC -- to train physicians in secondary and tertiary care hospitals in latest advances in the treatment of AIDS-related opportunistic infections. By the end of this summer, over 6,000 patients had already been treated in all nine provinces, and more than 3,000 health care providers have been trained -- and both of these numbers continue to grow.

Given its initial success, the programme is expected to continue for an indefinite period of time. In early June 2001, Pfizer announced its commitment to expand the Diflucan Partnership Programme beyond South Africa. Using the UN's list of least developed countries as a guide, Pfizer has expanded the initiative into many of the world's poorest countries most in need and into several southern African countries. This donation has no time or cost limitation and will result in Diflucan being made available, free of charge, to those countries most in need.

In addition to the provision of treatment, the programme seeks to enhance local capacity to manage HIV/AIDS related illnesses through training of health care professionals. In addition to product donations through the company, Pfizer and the Pfizer Foundation announced two major grants to support AIDS work in Uganda that will help to build infrastructure and to disseminate best practices. The first grant was awarded to a new organization, The Academic Alliance for AIDS Care, Treatment and Prevention, being spearheaded by leading ID experts in the US, Canada and Uganda. The group is building a training and care center at Makerere University and plans to train 80 health care providers per year in the latest techniques in HIV/AIDS diagnosis, treatment and prevention. The trainees are then expected to return to their communities and train others. In addition, the center plans to treat up to 50,000 patients per year when fully operational. Pfizer Inc and the Pfizer Foundation are projected to invest up to \$11 million during the development and start-up of this programme. The second grant, \$315,000 through the Pfizer Foundation, is to support a study led by UNAIDS, the Uganda AIDS Commission and UNICEF to identify community-based initiatives/best practices that have helped reduce HIV/AIDS prevalence rates in Uganda. Study results will be used in Uganda and other countries to help guide AIDS policy, strategy and programme development moving forward.

Impact

The impact of accelerating access should be assessed against the broad principles embodied in the Statement of Intent, as set out above. As a result of the momentum of accelerating access, many developing countries are devising comprehensive and long-term strategies for HIV/AIDS prevention, care and treatment. They have produced national strategies and plans that lay the foundation for sound and sustainable solutions. This is a painstaking and at times a frustrating process. On the other hand, it engenders collaboration among stakeholders committed to achieving tangible results and has established new forms of public/private partnership.

The information about the numbers of new patients treated with antiretrovirals as a result of accelerating access indicates that, while some progress has been made in some countries, it has not yet been able to deliver against the expectations generated. Over the two to five year planning horizon of twelve of the countries involved in agreements so far, the number of people living with HIV/AIDS who will have access to antiretrovirals over present access levels is forecast to be 30,900 (from a baseline of 6,500). The three middle income countries that have reached agreement with the pharmaceutical companies (Chile, Morocco and Romania) and Gabon, in sub-Saharan Africa, have committed to *universal* access to antiretrovirals for people living with HIV/AIDS. In the least developed countries, the costs of reduced price antiretrovirals are still high relative to income.

It can be argued that middle income countries have benefited most from the price reductions achieved to date, given their lower incidence of HIV infection and higher per capita incomes (eg with an HIV infection rate of 1.5%, universal access in Chile would cost 0.5% of GDP, compared with 17% in some sub-Saharan African countries).

The relatively limited impact of accelerating access on increasing the number of new patients treated can be explained by several factors, including:

- concern within the initiative to introduce antiretrovirals in a responsible manner, in the context of a comprehensive approach to care, in a way that would not jeopardise their use in future (through the avoidance of drug resistance);
- the need to ensure that reduced prices in the south do not constitute a threat to market prices in the north, and therefore to preserve the viability of antiretroviral drug development worldwide;
- the limited capacity of participating countries to rationally use the drugs and control their distribution; and
- limited funding, especially in countries where per capita health spending may be as little at US\$2.00 to \$20.00 a year – not enough to purchase even one month's therapy at currently feasible prices.

Accelerating access has had a positive impact on the know-how of caregivers with regard to the use of antiretrovirals. The national care and treatment plans serving as a collaboration tool with the pharmaceutical companies have a strong capacity-building component, including the training of caregivers. This element of the plan is essential to the avoidance of drug resistance.

The encouragement of a regional approach has served to promote networking among countries. This should have a positive impact on other elements of the global response to the HIV/AIDS epidemic.

As part of the Country Response Information System that will be launched by the UNAIDS Secretariat in collaboration with WHO towards the end of 2001, accurate data on the quality and impact of expanded treatment programmes will become available.

Constraints on increased access

Two main factors contributing to the low uptake of low-price antiretrovirals, despite the evident interest from so many countries, are limited infrastructure for managing patient care and for providing laboratory support, and limited funding to cover the cost of the drugs, laboratory reagents and other commodities. The lack of infrastructure and trained personnel in developing countries, the uncertain and inadequate finance for the total cost of care in the most affected countries, the reluctance to fund antiretroviral purchase on the part of many national governments and donors, and price levels that remain out of the reach of many developing country budgets mean that companies have not been able to report significant movement of products at this stage. There are high expectations that the Global AIDS and Health Fund will vastly increase the level of resources available to support a broad care agenda, including antiretrovirals.

Other constraints on scaling up access to HIV care in developing countries include uncertainty about the safest and most cost effective treatment regimens and difficulties with the establishment of safe, secure and effective procurement mechanisms.

Suggested areas for intensified joint action

The UN and the research-based pharmaceutical industry should work together more intensively to address these constraints and to increase the impact of initiatives on accelerated access to HIV care and support.

I. **Global AIDS and Health Fund** – there is considerable interest in increasing the resources available for HIV/AIDS care and support, including funding for the purchase of needed medicines. The transitional phase of the establishment of the Global AIDS and Health Fund, when the scope, shape and purpose of the Fund are being determined, provides the opportunity to pursue this. The leading role of pharmaceutical companies in the business community can help encourage private sector involvement, leading to a more effective global response.

II. **Regional perspectives and care initiatives within countries** – active support of regional initiatives to collaborate on improved access to care, along with further extension of discounted prices to accredited private sector and not-for-profit care providers and greater activity in middle income countries would serve to increase the impact of accelerated access more quickly.

III. **Infrastructure development and training** – increased participation of the private sector alongside UN technical agencies in the development of health care infrastructure, including support for human resources development, improved laboratory and diagnostic facilities and quality control measures, could help provide better care for people with HIV.

IV. **Operational and clinical research agenda** – greater sharing of ideas between the UN system and the private sector on an appropriate research agenda and better mechanisms for communication of research in progress, with a particular emphasis on optimal care regimens for resource-poor settings and optimal approaches to monitoring effectiveness and safety, could increase the effectiveness of investment in research and development. The UN and industry should continue to ensure a positive legal, trade and commercial framework is in place to encourage more intensive and broader investment in biological and medicinal product research and development for diseases primarily affecting the developing world.

COUNTRIES THAT HAVE EXPRESSED INTEREST IN ACCELERATING ACCESS

Countries	Completed/advanced planning	Agreement on prices/ national plans ^{††}
AFRICA (40)		
Algeria		
Angola		
Benin		
Botswana		
Burkina Faso	yes	yes
Burundi	yes	yes
Cameroon	yes	yes
Cap Vert		
CAR	yes	
Chad	yes	
Congo (DRC)		
Cote d'Ivoire	yes	yes
Ethiopia	yes	
Gabon	yes	yes
Gambia	yes	
Ghana		
Guinea	yes	
Guinea-Bissau		
Kenya	yes	
Lesotho		
Liberia		
Malawi	yes	
Mali	yes	yes
Mauritius		
Morocco	yes	yes
Mozambique		
Namibia		
Niger		
Nigeria		
Rwanda	yes	yes
Sierra Leone		
Senegal	yes	yes
Seychelles		
South Africa		
Swaziland	yes	
Togo	yes	
Uganda	yes	yes
Tanzania		
Zambia		
Zimbabwe		

^{††} Countries which, with involvement from UNAIDS, have reached agreement on reduced drug prices in the context of national plans. Individual companies have reached agreement with additional countries.

LATIN AMERICA/CARIBBEAN (24)		
Antigua & Barbuda		
Bahamas		
Barbados	yes	
Belize		
Chile	yes	yes
Costa Rica		
Domenica		
Grenada		
Guatemala		
Guyana		
Haiti		
Honduras		
Jamaica		
Mexico		
Montserrat		
Nicaragua		
Panama		
San Salvador		
St Kitts & Nevis		
St Lucia		
St Vincent/Grenadin		
Suriname		
Trinidad and Tobago	yes	yes
Venezuela	yes	
EUROPE (4)		
Belarus		
Moldavia		
Romania	yes	yes
Ukraine	yes	
SOUTHEAST ASIA (3)		
Malaysia		
Thailand		
Vietnam	yes	

PRICES OF ANTIRETROVIRAL MEDICINES IN LEAST DEVELOPED COUNTRIES AND GENERIC VERSIONS

Drug	Price of drugs from individual R&D companies in Least Developed Countries in Africa, April 2001 (US\$/ defined daily dose)	Price of drugs from individual R&D companies, December 2000 (US\$/defined daily dose)	Lowest price generic drugs* April 2001 (US\$/defined daily dose)
Nucleoside RT inhibitors			
Zidovudine (ZDV)	1.60 (GSK)	TBA	0.53 (Hetero)
Zidovudine plus lamivudine combination (ZDV + 3TC)	2.00 (GSK)	2.00	
Lamivudine (3TC)	0.64 (GSK)	0.64	0.25 (Aurobindo)
Abacavir	3.80 (GSK)	TBA	
Abacavir +3TC+ZDV	6.60 (GSK)		
Zalcitabine (ddC)	1.80 (Roche)	2.44 (Roche)	
Didanosine(ddl)	0.85 (BMS)	0.85	0.52 (Aurobindo)
Stavudine (d4t)	0.15 (BMS)	0.75	0.11 (Cipla. to not-for-profit programmes)
Non-nucleoside RT inhibitors			
Nevirapine	1.20 (free for MTCT) (BI)	1.20	0.54 (Cipla. to not-for-profit programmes)
Efavirenz	1.37 (Merck)	2.93	1.33 (Aurobindo)
Delaviridine			
Protease Inhibitors			
Amprenavir	8.70 (GSK)	TBA	
Saquinavir (Invirase)	1.56-3.91 ^{with riton} 3.52 ^{licensed d} (Roche)	3.80-9.49 ^{with riton} 8.54 ^{licensed d} (Roche)	
Saquinavir	1.56-3.91 ^{with riton}	2.37-5.93 ^{with riton}	

* Information on prices provided by R&D companies or taken from “[Sources and prices of selected drugs and diagnostics for people living with HIV/AIDS](#)”, WHO, UNICEF, the UNAIDS Secretariat and MSF, June 2001. GSK prices based on \$1.60/£

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(Fortovase)	7.03 ^{licensed d} (Roche)	10.68 ^{licensed d} (Roche)	
Nelfinavir (tablets)	9.06 (Roche)	9.06 (Roche)	
Nelfinavir (pediatric powder)	2.98** (Roche)	2.98** (Roche)	
Lopinavir/Ritonavir	1.78 (Abbott)	N/A	
Indinavir	1.64 (Merck)	2.70	5.04 (Cipla)

*

- Price of saquinavir when used in combination with ritonavir at a dose of SQV/RTV 400mg/400mg BID and in investigational regimens of SQV/RTV 1000mg/100mg BID and 1600mg/100mg once-daily being evaluated in African CARE, Thai STACCATO and HIV-NAT programs and in developed world clinical trial programs. These prices do not include ritonavir component of the regimen.
- These prices represent ex-Manufacturer prices and do not take into account potential import duties and taxes, and Agent, Wholesaler and Pharmacy trade margins. Prices are as of Sept 2001.
- Calculated on the weight of an 8 kg child at the maximum recommended dose of 30mg/kg TID

**JOINT UN/UNAIDS/WHO
PRESS RELEASE**

**THE UNITED NATIONS SECRETARY GENERAL TO LEAD THE FIGHT AGAINST
HIV/AIDS**

Amsterdam, 5 April 2001 – The Secretary General of the United Nations, Kofi Annan, today met with six of the world's leading pharmaceutical companies to agree what further steps need to be taken to improve access to better healthcare, HIV medicines and HIV-related medicines for developing countries as part of further action to combat AIDS, including prevention, education and research.

The Secretary General met with CEOs and senior executives of six pharmaceutical companies (Abbott Laboratories, Boehringer Ingelheim, Bristol-Myers Squibb, GlaxoSmith Kline, Hoffmann-La Roche, and Pfizer). At the meeting, the Secretary General was joined by Gro Harlem Brundtland, Director-General of the World Health Organization, and Peter Piot, the Executive Director of the Joint United Nations Programme on HIV/AIDS (UNAIDS).

The companies have made significant progress individually in providing an expanded number of drugs to combat AIDS, including antiretrovirals and treatments for opportunistic infections. Prices have come down substantially as a result of the companies' individual actions. The Secretary General urged them to continue and accelerate these initiatives. Special emphasis was placed on the Least Developed Countries, particularly those in Africa, as well as the need for continued country-by-country negotiations in other developing countries. All recognized that qualified non-governmental organizations and appropriate private companies offering healthcare to employees and local communities in these nations should also be considered for increased accessibility to HIV/AIDS medicines.

"Encouraging the active participation of all partners in the fight against AIDS has become my personal priority," said Kofi Annan in a statement released today. "The epidemic is the greatest public health challenge of our times and we must harness the expertise of all sectors of society. The pharmaceutical industry is playing a crucial role. We need to combine incentive for research with access to medication for the poor. Intellectual property protection is key to bringing forward new medicines, vaccines and diagnostics urgently needed for the health of the world's poorest people. The UN fully supports the TRIPS agreement - including the safeguards incorporated within it. However, the solution does not lie with the pharmaceutical companies alone. I am calling for a major mobilisation - of political will and significant additional funding - to enable a dramatic leap forward in prevention, education, care and treatment."

The companies include four – Boehringer Ingelheim, Bristol-Myers Squibb, GlaxoSmith Kline and Hoffmann-La Roche – which last year signed a Statement of Intent with five United Nations agencies within the Accelerating Access endeavour in which they committed to explore practical and specific ways of working together more closely to accelerate access to HIV/AIDS-related care and treatment in developing countries. During this time, agreements have been reached between the companies and five countries, Cameroon, Côte D'Ivoire, Rwanda, Senegal and Uganda. Today's discussion builds upon and seeks to expand the progress made to date. This includes efforts made to increase the availability of interventions to reduce the incidence of mother-to-child transmission.

"The HIV epidemic demands nothing less than a radical transformation of how we approach health care in developing countries," said Dr Piot, "Many issues must be addressed if care and treatment in the developing world are to be improved, and affordability of medicines is an intrinsic part of such a comprehensive health care strategy."

“Access to affordable medicines is a key element in improving both care and prevention,” Dr Brundtland. “Affordable drugs will catalyze greatly increased attention to voluntary counselling and testing, effective healthcare delivery systems, and innovative funding mechanisms.”

In a number of countries, decades of development are being reversed by HIV, the virus that causes AIDS. Some 36.1 million people are living with HIV or AIDS worldwide, with 5.3 million newly infected during 2000 alone. That same year, 3 million people died of AIDS, bringing the total number of deaths since the start of the epidemic to 21.8 million.

The spread of the epidemic and its devastating impact on humanity alarmed the United Nations and prompted it to convene a Special Session of the General Assembly on HIV/AIDS at the highest political level. To be held from 25-27 June in New York, the Special Session will focus the world's attention on the epidemic. It aims to intensify international action to fight the spread of HIV/AIDS and to mobilize the additional resources that will be needed.

For more information, please contact Anne Winter, UNAIDS, Geneva, (+41 22) 791 4577, Dominique de Santis, UNAIDS, Geneva, (+41 22) 791 4509, Ria Heremans, UNIC, Brussels, mobile, (+32 47) 621 5485 or Andrew Shih, UNAIDS, New York, (+ 1 212) 584 5024. You may also visit the UNAIDS Home Page on the Internet for more information about the programme (<http://www.unaids.org>).

AMSTERDAM STATEMENT

THE SECRETARY-GENERAL

Statement after meeting the leaders of six leading research-based
pharmaceutical companies

Amsterdam, 5 April 2001

I met today in Amsterdam with the top executives from six leading multinational pharmaceutical companies, along with Dr. Gro Harlem Brundtland, Director-General of the World Health Organization, and Dr. Peter Piot, Executive Director of UNAIDS, to discuss what further steps can be taken by these companies to make care and treatment more accessible for people living with HIV/AIDS in developing countries.

The way we have dealt with the needs of the developing world in recent years is simply not adequate. We need a radically different approach, and all sectors of society must be involved.

I called for this meeting because encouraging the active participation of all partners in the fight against AIDS has become my personal priority. The epidemic is the greatest public health challenge of our times and we must harness the expertise of all sectors of society. The pharmaceutical industry is playing a crucial role. I would also want to applaud the contributions by non-governmental organizations, who are our vital partners in this fight. We need to combine incentive for research with access to medication for the poor.

Intellectual property protection is key to bringing forward new medicines, vaccines and diagnostics urgently needed for the health of the world's poorest people. The UN fully supports the TRIPS agreement -- including the safeguards incorporated within it.

However, the solution does not lie with the pharmaceutical companies alone. I am calling for a major mobilisation -- of political will and significant additional funding -- to enable a dramatic leap forward in prevention, education, care and treatment.

I am pleased to tell you that the companies have today agreed to do the following:

First, to continue and accelerate reducing prices substantially, with a special emphasis on the Least Development Countries, particularly those in Africa.

Second, to continue to offer affordable medicines to other developing countries, on a country by country basis.

Third, to recognize the need to consider increased access to HIV/AIDS medicine to qualified non-governmental organizations and appropriate private companies offering health care to employees and local communities in these nations.

Today's commitments consolidate, and go beyond, the progress which individual companies had made in reducing prices since last May, when five of them signed a Joint Statement of Intent with the United Nations. This represents a contribution to the global response to the epidemic, going much further than any of us could have predicted twelve months ago.

At the same time, we must not forget that the price of drugs is only one of the issues that has to be addressed in improving the quality of care and treatment for HIV/AIDS affected people in the developing world. Drugs can only work if they form part of a comprehensive approach, which runs from voluntary counseling and testing to home and community-based care, and simple treatments for opportunistic infections. And, of course, our highest priority must still be to ensure that fewer people become infected with HIV in the first place.

None of these things can be achieved without spending a lot more money. IN the next few months, leading up to the Special Session of the General Assembly at the end of

June, the United Nations will be working overtime to mobilise increased resources for all aspects of the struggle against HIV/AIDS, and for better health care in developing countries.